The Effect of Pelvic Floor Re-education on Comfort In Women Having Surgery for Urinary Incontinence

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Dedications

This research is dedicated to my husband,

Joseph Zaccardi

whose love and support made it possible

And to my children,

Diane, Joseph and Margot

whose belief in me is truly my inspiration.

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Abstract

The Effect of Pelvic Floor Re-education on Comfort
In Women Having Surgery for Incontinence
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The purpose of this study was to examine the effect of a pelvic floor re-education intervention on comfort and stress urinary incontinence in women opting for surgical correction and to explore the patient's feelings regarding the ease and benefit of attending the pelvic floor re-education intervention. The following research hypotheses were tested: H_1 = comfort scores will increase across time and amount of urine leaks will decrease across time in women having surgery for stress urinary incontinence. H_2 = women in the pelvic floor re-education intervention group will have greater comfort as compared to women in the control group who do not have the pelvic floor re-education intervention and H_3 = women in the pelvic floor re-education intervention group will have less stress incontinence as compared to women in the control group who do not have the pelvic floor re-education intervention. Stress urinary incontinence is a significant women's health problem because of its prevalence, cost and social implications. Current treatment strategies consist of pelvic floor re-education, behavior modification or surgical correction. Surgery for stress urinary incontinence yields a high objective cure. However, many women indicate dissatisfaction with surgical outcome related to voiding dysfunction and discomfort. Therefore, comfort is a nursing goal that can be used as a holistic outcome measurement in women having surgery for stress incontinence. This was a preliminary exploratory study using a quasi-experimental mixed model design. Twenty-eight women scheduled for corrective surgery for stress urinary incontinence were

randomly assigned to the control and treatment groups. Subjects were measured at three time points on comfort and stress urinary incontinence. The primary statistical analysis was mixed model analysis of variance (ANOVA). Results from the Greenhouse-Geisser corrected mixed model ANOVA revealed that only the main effect of time was significant for differences in comfort scores. Knowledge gained from this study can be used to direct further research. A larger study with adequate sample size and power will contribute to the advancement of nursing science and may translate into improved patient outcomes in the practice settings.

CHAPTER 1: INTRODUCTION AND OVERVIEW

Introduction

The prevalence of urinary incontinence is high throughout the world and urinary incontinence is twice as common in women as in men (Diokno, 2002). Many women will alter their lifestyles rather than face the social humiliation of incontinence. Women usually have urinary symptoms for over two years before seeking medical treatment because of the embarrassment and stigma associated with this condition (Abrams, Cardoza, Saad & Wein, 2002; Garcia, Crocker & Wyman, 2005; Kitchin et al., 2003).

Urinary incontinence has an economic impact on society that is related to the cost of evaluation, treatment, and adverse health related consequences. The annual cost of urinary incontinence in the United States is estimated to be between 16 and 26 billion dollars (Wagner & Hu, 1995). Comparative studies performed by the US National Institute of Health reported that female urinary incontinence has a higher direct cost than other diseases in women, including osteoporosis, breast and gynecological cancers, and arthritis (Abrams et al. 2002). Because of the prevalence, high financial and social burden, and impact on women's health, urinary incontinence is a major health problem requiring attention from health care professionals and the consideration of nurse researchers.

Background

Stress urinary incontinence, a subtype of incontinence, occurs when there is weak urethral resistance in response to increased intra-abdominal pressure (Abrams et al., 2002). Stress urinary incontinence affects 15% - 60% of women over their lifetime and is the most common type of incontinence in women younger than age 65 (Melville et al., 2005). Surgery is commonly performed for stress urinary incontinence and yields a high

physical cure rate that is defined as an absence of leakage with exertion (Abrams et al.; DeBeau, 2006). Other outcomes that are used to measure response to treatment include: number of daytime and nighttime voids, complaints of urgency or frequency and post void residual volume. However, these objective measures are not always congruent with a patient's perception of improvement. According to Deval, Jeffry, Najjar, Soriano and Darai (2002) the objective cure of incontinence surgery appears to be higher than the subjective one. Women often describe difficulty emptying their bladder along with feelings of irritation and discomfort as causes of dissatisfaction with surgical outcomes even though urinary leakage is improved (Deval et al.). Surgical outcome can be better assessed from the patient's perspective with the holistic concept of comfort. Nurses routinely identify the comfort needs of their patients and design interventions to meet these needs. Therefore, nursing interventions that enhance comfort support the goals of surgical correction of stress urinary incontinence.

In addition to surgery, treatment options for women with stress urinary incontinence consist of pelvic floor re-education and/or behavior modification. Although previous research supports the efficacy of these individual treatments (Wilson, Bo, Hay-Smith et al. 2002), gaps in the literature exist for combining these treatment strategies. A review of the literature regarding surgery and pelvic floor re-education as treatment for female stress urinary incontinence revealed no systematic studies to determine the effect of a combination of therapies on comfort and stress incontinence in women having corrective surgery.

The rationale for this research is that women who receive a pelvic floor re-education intervention during the weeks prior to surgery may have an increase in comfort

and a decrease in stress urinary incontinence following the intervention and post-operatively. It is postulated that by attending the pelvic floor re-education sessions women will have a sense of awareness of the role of pelvic muscles in bladder function, have more information regarding their surgery and post operative recovery, and have the potential to increase strength and tone of the pelvic floor muscles. This, in turn, may facilitate wound healing, enhance comfort and support elimination following surgery.

Physical muscle exercise is routinely performed prior to and following orthopedic surgery as part of a comprehensive treatment plan in order to prevent loss of function and improve surgical outcomes (Jones et al., 2005). A landmark study by Kegel (1948) reports exercise is an accepted and well known strategy in restoring function in injured skeletal muscles and should be considered in improving performance of pelvic floor muscles.

The present study employed two formal biofeedback sessions in which instruction on the performance of pelvic muscle exercise provided the patient with an awareness of coordination, strength, and relaxation of these muscles as well as individualized instruction of behavior modification for general bladder health. Potentially this intervention will increase comfort post operatively and decrease voiding difficulties, incomplete bladder emptying, and defecation straining that are the most common complaints following incontinence surgery (Davis, Lukacz, Luber, & Nager, 2004; Elkadry, Kenton, Fitzgerald, Schott & Brubaker, 2003; Lukban, 2005; Mishra, Mishra, Karim, Motiwala, 2005).

This investigation is a preliminary, exploratory study that will guide development of a larger study. Burns and Grove (2007) indicate that in addition to gaining knowledge

research is influenced by the cost of conducting the study and the amount of money available to the researcher. This study was self funded by the researcher, and therefore was undertaken to refine the steps in the research process and assess the possibility of obtaining funding for a larger study. The outcomes of this study will direct further research which in turn will lead to knowledge and evidence based practice for nursing.

This study is based on the conceptual framework of Comfort Theory (Kolcaba, 1994). According to this theory comfort needs arise from a stimulus that causes negative tension and encompass physical, psychospiritual, environmental and social aspects of comforting measures (Kolcaba). A number of research studies, based on this framework, using nursing interventions have demonstrated an increase in comfort in various settings and populations (Dowd, Kolcaba & Steiner, 2000; Dowd, Kolcaba & Steiner, 2002; Kolcaba & Fox, 1999; Kolcaba & Wilson, 2003; Wilson & Kolcaba, 2004). A study by Dowd et al., (2000) reported that comfort scores, measured by the Urinary Incontinence and Frequency Comfort Questionnaire (UIFCQ), were increased in patients with urinary leakage and/or frequency that participated in a cognitive behavioral intervention for bladder health. According to Dowd et al. comfort scores are a strong predictor of the benefits from behavioral treatment for urinary leakage and frequency.

This present study utilized comfort as the goal of a nursing intervention and this outcome was measured by both subjective and objective patient perspectives. According to the conceptual framework of comfort theory (Figure 1), the obstructing force is health care needs associated with stress urinary incontinence and corrective surgery. Interacting forces of intervening variables are age, weight, parity, ethnicity, socioeconomic status, education and concomitant surgeries (such as repair of pelvic organ prolapse including

bladder, rectum and uterus). The facilitating force (pelvic floor re-education) was introduced as a nursing intervention, thereby addressing the four contexts in which comfort is experienced (physical, psychospiritual, environmental and social). According to the conceptual framework the intervention encourages the patient to move toward attainment of comfort and seek healthy behaviors.

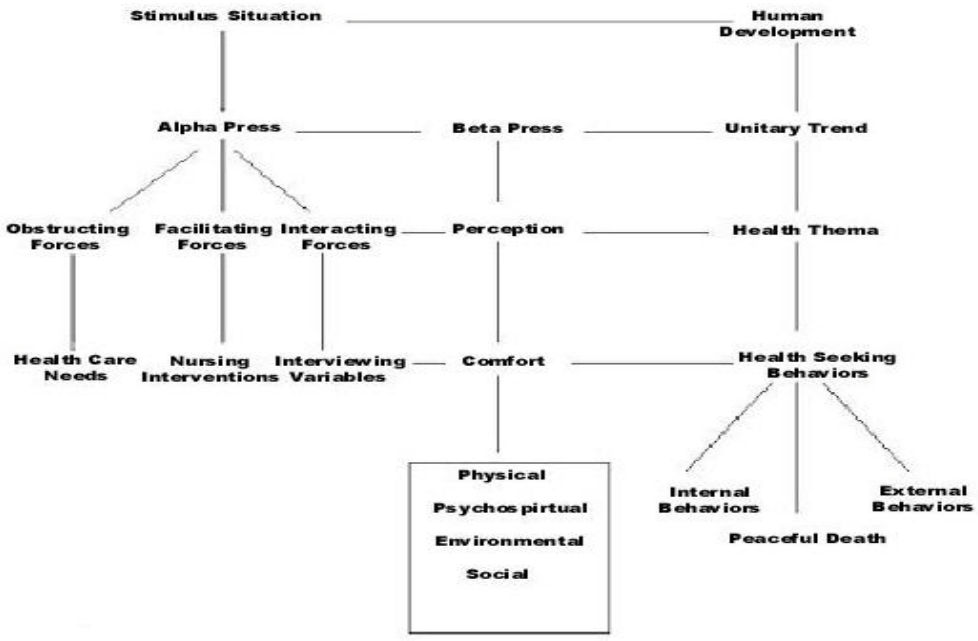

Figure 1 Comfort Theory (from TheComfortLine.com 2008).

Purpose

The purpose of this preliminary exploratory study is to examine the effect of a pelvic floor re-education intervention on comfort and stress urinary incontinence in women opting for surgical correction and to explore the patient's feelings regarding the ease and benefit of attending the pelvic floor re-education intervention. In addition, results from this study will be used to determine if a larger study is warranted. The long-term goal of this study is to support a full study thereby endorsing the development of

clinical protocols using pelvic floor re-education as a means to enhance comfort and decrease urinary leaks in women having surgery for stress urinary incontinence.

Research Questions

The following research questions were addressed in this study: (1) Is there an effect of time on the dependent variables, comfort and stress urinary incontinence? (2) Is there an effect of a pelvic floor re-education intervention on comfort in women having incontinence surgery? (3) Is there an effect of a pelvic floor re-education intervention on amount of urinary leakage in women having incontinence surgery? (4) Do the participants in this study consider the intervention worth their time? (5) Does this study support the feasibility of a larger study?

The specific aims of this study included the following: (1) evaluate the effect of time on comfort and stress incontinence in women having corrective surgery. The working hypothesis is that there is an effect of time on the dependent variables. Therefore, H_1 states comfort scores will increase across time and amount of urine leaks will decrease across time in women having surgery for stress urinary incontinence. (2) Evaluate pelvic floor re-education as an intervention that enhances comfort in women having surgery**.** The working hypothesis is that there is an effect of a pelvic floor re-education intervention on comfort. Therefore, H_2 states women in the pelvic floor re-education intervention group will have greater comfort as compared to women in the control group who do not receive the pelvic floor re-education intervention. (3) Evaluate the effect of pelvic floor re-education on stress urinary incontinence prior to and following surgery. The working hypothesis is that there is an effect of a pelvic floor re-education intervention on stress urinary incontinence. Therefore, H_3 states women in the

pelvic floor re-education intervention group will have less stress incontinence as compared to women in the control group who do not receive the pelvic floor re-education intervention. (4) Explore the patient's perception of the intervention and the hardship of attending the intervention sessions. (5) Evaluate the feasibility of conducting a larger study by considering the cost, safety and acceptability of the intervention, and the success of recruiting as well as the retention of participants.

Significance

Urinary incontinence is a women's health problem that affects women in every age group and is relevant to nursing because of its prevalence, cost and social implications. According to Lukban (2005) urinary incontinence causes discomfort which negatively impacts the physical, psychological and emotional well being of the patient. Review of the literature provides nurses with limited evidence in improving comfort in women having surgery for stress urinary incontinence. Advanced practice nurses have the responsibility to evaluate and manage women with urinary incontinence by adopting evidence based guidelines and designing treatment protocols.

A positive relationship between preoperative exercise and post operative functional status, comfort, and patient satisfaction is documented in orthopedic knee and hip surgical outcomes (Gilbey et al., 2003; Jones et al., 2005). Therefore, combining pelvic floor re-education with incontinence surgery may facilitate normal bladder function and increase a patient's post operative comfort and their perception of a successful surgical outcome.

Patient-based outcomes may be appropriately assessed using comfort because it is a holistic concept achieved through fulfillment of healthcare needs (Dowd, Kolcaba, &

Steiner, 2000). Comfort is a traditional outcome of a nursing intervention and can be assessed for effectiveness when specific patient needs are addressed (Kolcaba, 1994). This study focuses on comfort as an outcome measure of the patient's perception of improvement following a nursing intervention.

Considering the prevalence, cost and social implications of female urinary incontinence along with the high cure rate of surgical intervention, this study is significant because it is expected to provide knowledge that is needed to determine the effects on comfort and stress incontinence by combining a nursing intervention with surgical correction. As the present evidence of the benefit of this intervention is limited, this study will help direct future research. Once these effects are determined treatment protocols to improve comfort following surgery and decrease urinary incontinence can be developed which will potentially reduce health care costs by decreasing the burden of living with stress urinary incontinence

Definition of Terms

Stress Urinary Incontinence

The International Continence Society (ICS) has standardized the terminology associated with lower urinary tract function (Abrams et al., 2002). The aim of this published report is to facilitate comparison of research results and communication of these results among investigators. The current definitions are updated from the previous ICS report and are compatible with the World Health Organization's publication of International Classification of Functioning, Disability and Health (ICIDH) and the International Classification of Diseases (ICD). The ICS report explains urinary

incontinence in terms of signs, symptoms, urodynamic observations, and conditions related to lower urinary tract dysfunction.

The present definition states the symptom of urinary incontinence is the complaint of any urine leakage that is involuntary (Abrams et al., 2002,) while urinary incontinence (the sign) is defined as observed urine leakage seen during examination (Abrams et al., 2002). Urinary incontinence can occur when any of the normal functions of the bladder are disrupted (Palmer, 2003). Subtypes of urinary incontinence are defined according to specific circumstances and underlying etiology. ICS defines stress urinary incontinence as the complaint of involuntary leakage on effort or exertion, or during sneezing or coughing. (Abrams et al. 2002)

For the purpose of this investigation stress urinary incontinence was initially diagnosed with urodynamic studies and then further operationalized using the paper towel test (Miller, Ashton-Miller, & Delancey, 1998). According to Miller et al. the paper towel test is a noninvasive and reliable method for observing stress urinary incontinence. It can also quantify the leakage of urine once a diagnosis is made by measuring the wet spot and using the "paper towel test look up table" (Appendix A) to mathematically convert the measurement to milliliters (Miller et al.).

Comfort

According to Kolcaba and Kolcaba (1991) the concept of comfort includes both physical and psychological experiences. "Comfort is defined for nursing as the satisfaction (actively, passively, or cooperatively) of the basic human needs for relief, ease, or transcendence arising from healthcare situations that are stressful." (p.1307). Kolcaba (1994) further defines comfort as meeting these needs in four contexts; physical,

psychospiritual, social, and environmental. A person achieves relief when needs are met; ease refers to a positive "state of calm or contentment" (Kolcaba, 2003, p. 15). Transcendence is explained as feeling that one is strengthened, that is, a person "transcends" or rises above the stressor. For the purpose of this study, comfort was defined as a holistic outcome associated with the ease, relief and transcendence of the stressor, stress urinary incontinence. Comfort was operationalized by the participant's total score on the Urinary Incontinence and Frequency Comfort Questionnaire (UIFCQ) (Appendix B) which consists of 27 statements specific to feelings associated with living with urinary incontinence (Dowd et al., 2000).

Pelvic Floor Re-education

Pelvic floor re-education is a term that describes a process used to restore urinary continence in adults (Davila, Ghoniem, & Wexner, 2006). It involves a program of patient education that includes performance of pelvic muscle exercise and information regarding bladder function, general bladder health, and proper toileting habits. The process aims to decrease bladder urgency and incontinent episodes using muscle strengthening exercises, such as Kegel exercises, thereby increasing a patient's confidence in their ability to control elimination (Wilson, Bo, Hay-Smith et al., 2002).

Pelvic floor re-education can be instructed with and without the use of biofeedback. Biofeedback is an external source of information and a method for providing individuals with information upon which self regulation of bodily functions are based. During biofeedback, a bodily function is brought into awareness by visually or audibly displaying the function; this allows conscious access that can possibly work, with practice, to change the function (Lovallo, 2005). Initially performance of pelvic floor re-

education involves learning the correct muscles to contract and relax. Biofeedback is a useful teaching aid in assisting people to identify these muscles and perform the exercises properly as well as provide a means of motivation to continue the pelvic muscle exercises between formal sessions (Hiser, 1999). In the present study, pelvic floor re-education was instructed with the aid of biofeedback.

Limitations

The small sample size and the use of a convenience sampling limit the results and generalizability of this study. Due to economic considerations this study was under powered. Generalizability is also limited by the homogeneity of the sample. However the subjects participating in this study are likely to be similar to other women with a diagnosis of stress urinary incontinence seen in an urogynecology specialty practice. Another limitation was the short post operative follow-up period of 3 weeks. Longer follow-up would confirm the results or uncover more or less favorable results over time.

Delimitations

The sample was delimited to female patients who were having surgery to correct stress urinary incontinence. Those women between the ages of 35 to 80 were eligible to participate in the study. This study focused exclusively on women due to the prevalence, nature of the condition, the treatment of surgical correction by the urogynecologist and the intervention. Pregnant women did not participate in the study because surgery for stress urinary incontinence is not performed during pregnancy. The sample of convenience included recruitment of all adult women who met the criteria regardless of race or ethnic background. Children were not included in this study because this surgery is not performed on children. To minimize data error, patients who were able to read and

understand the English language, as determined by the investigator, were enrolled in the study.

Summary

In summary, this study examined the effect of a pelvic floor re-education intervention on two dependent variables, comfort and stress incontinence. Three hypotheses were tested to determine if pelvic floor re-education effects comfort and stress urinary incontinence in women having corrective surgery. Stress incontinence and surgery can result in irritation and discomfort for patients. Implementing and evaluating a nursing intervention to increase comfort, decrease incontinence and potentially alleviate distress is paramount in nursing care. Therefore, testing of these outcomes provided knowledge regarding the use of such an intervention prior to surgery. Results of this study will direct further research and explore the patient's perception of the intervention.

CHAPTER 2: REVIEW OF THE LITERATURE

Introduction

The Agency for Healthcare Quality and Research, guidelines for clinical practice, recommend the application of a multifactorial stepped approach to treating urinary incontinence (Fantl et al., 1996). A plan of care should focus on assessment of the patient, identification of risk factors, treatment of reversible conditions, and implementation of a strategy that is consistent with the patient's diagnosis and goals (Fantl et al.). According to Kolcaba, Tilton and Drouin (2006) comfort is a measurable objective of the nurse-patient interaction and remains a primary function of nursing care. Kolcaba (2003) states that comfort is an outcome that is particular to the discipline of nursing because it is positive, reflects the standards of nursing practice and influences the patients' perception of health and satisfaction with care. Many comfort needs are associated with urinary incontinence. Thus, comfort is an appropriate dependent variable for nursing research focused on urinary incontinence.

A knowledge deficit exists regarding the effect of a combination of therapies on comfort and stress urinary incontinence in women having surgery. Although previous research indicates that surgery or pelvic floor re-education are effective treatments for stress incontinence, no studies have been found that determine the effect of a pelvic floor re-education intervention on comfort in women having surgical correction of stress urinary incontinence.

Stress Urinary Incontinence

Surgery, specifically the pubovaginal sling procedure, was first described in the early 1900's and is considered the gold standard for the treatment of female stress urinary

incontinence (Schorge et al., 2008). The physiology of the sling is to support the bladder neck and compress the proximal urethra, preventing its descent during times of increased intra-abdominal pressure, thus decreasing leakage of urine with exertion. The sling procedure has evolved and progressed throughout the past hundred years. New materials and minimally invasive approaches have improved cure rates and decreased complications (Schorge et al.).

The patients in this study all underwent the pubovaginal sling Gynecare TVT™ procedure, in which a mesh ribbon or tape, is placed vaginally under the urethra and exits at or near the thigh crease. The study was limited to this procedure because according to Ward and Hilton (2002) it is difficult to compare different surgical procedures due to the variability of the procedures and the skill and experience of the surgeon. To minimize data error all patients in this study underwent the Gynecare TVT™ pubovaginal sling; all surgery was performed by one surgeon in the same hospital.

Review of the literature revealed that comparison of objective rates of cure was similar for women undergoing the Burch procedure (surgical procedure that has had effective cure rates) and those having the sling (Ward & Hilton, 2002; Ward & Hilton, 2004; Young, Howard & Baker, 2001). Ward and Hilton (2002) reported that the objective cure rates measured by the pad test and urodynamic cystometrogram were equivalent. Subjective cure rates, based on the patient's report, were also similar, 59% in the pubovaginal sling group versus 53% in the Burch group. It is interesting to note that although the sling procedure had a post operative recovery course with decreased analgesia needs, shorter hospital stays, less catheterization and a sooner return to work time, there was no difference in the patients perception of cure (Ward & Hilton, 2002).

According to Nygaard and Heit (2005) the most common complication of the pubovaginal sling is urinary retention due to urethral obstruction. Two similar studies revealed urinary frequency and overactive bladder symptoms as additional post operative complications related to this type of surgery (Nygaard & Heit; Paraiso, et al., 2005).

Six recent studies examined the subjective outcomes of women having pubovaginal sling surgery (Bradway, 2003; Davis et al., 2004; Jeffry et al., 2001; Jomaa, 2001; Richter et al., 2005; Tomoe et al., 2005). Davis evaluated patient satisfaction related to surgery and reported that a decrease in satisfaction was related to post operative complications that interfere with normal bladder function. Jeffrey et al. correlated a decrease in patient satisfaction with de novo overactive bladder symptoms. The four other studies measured quality of life to determine the subjective satisfaction with improvement as it relates to a patients quality of life (Bradway; Jomaa; Richter et al. Tomoe et al.). Common to all of the above studies is that the objective success of anti-incontinence surgery did not necessarily coincide with the patients subjective results. Satisfaction and quality of life scores were lower in patients having issues with bladder function regardless of the amount of urinary leakage on exertion.

Comfort

Comfort is considered an important aspect of healthcare and can measure the effectiveness of a nursing intervention. This concept has multidimensional considerations and appears in nursing, as well as medical, psychosocial and ergonomic research literature (Cox & Davidson, 2005). Although each discipline has its unique perspective on comfort, nursing approaches comfort from a holistic viewpoint incorporating physical, psychosocial, emotional, spiritual, and environmental qualities to the conceptualization

(Benner, 1984; Gropper, 1992; Hamilton, 1989; Hurley, Volicer & Mahoney, 2001; Kolcaba, 1992; Kolcaba & Kolacaba, 1991; Malinowski & Stamler, 2002; Morse, 1983).

The concept of comfort appears to have originated in the nursing literature during development of the modern nursing era. Nightingale (1969) noted that health of the person was directly associated with comfort. In her writings on observation Nightingale stressed the importance of *sound observation* and cautioned nurses to remember the purpose of observation. That is, to increase health and comfort of the patient. Although Nightingale did not formally define comfort, she related the concept to both physical and mental states giving it a holistic connotation. Nightingale recognized comfort as a nursing outcome and described nursing actions used to achieve this goal (Gropper, 1992). Kolcaba (1991) and Morse (1992) agree that comfort is a multidimensional endeavor seen across the life-span and is most often recognized as a nursing action and/or desired outcome. Gropper reports that comforting actions encompass a nurse-patient relationship in which needs are identified, understood and ultimately met. This is a dynamic relationship because needs are constantly changing, are then reassessed and responded to. Gropper defines health as physical and emotional comfort. She believes that comfort is not only a nursing objective but should be considered a primary patient goal. Kolcaba (1995) describes comfort as a nursing outcome or "product" of nursing care. According to Kolcaba nursing care is actually comfort care or the "process" of achieving the goal of comfort. This description is further explained as a rationale for nursing actions or interventions that are purposely directed toward achieving the product of comfort. Kolcaba recognizes comfort as a holistic outcome because each action includes addressing needs of the patient and family. Meeting some comfort goals will positively

influence other comfort needs and some non-specific interventions will provide total comfort for some individuals (Kolcaba).

The review of the literature revealed a number of qualitative research studies on the concept of comfort. A total of nine studies using various qualitative methods appeared in the nursing literature between 1990 and 2008 along with one unpublished doctoral dissertation. Two classic studies from 1983 and 1989 were also included in this analysis to provide a historical perspective. Summary of the qualitative research studies on comfort in nursing reveal similar intentions: to explore the meanings and attributes of the concept, to identify common themes of comfort from patients' perspective, and to define comfort for nursing research and practice. Four of the qualitative studies were conducted by Janice Morse. Two studies, Morse (1983) and Hamilton (1989) are considered landmark studies and are referenced by other authors in subsequent publications. Seven of the studies used interview as the method of data collection, two were review of the literature, one employed participant observation and one, non-participant observation. Designs of the research varied and included ethnographic, exploratory, historical, phenomenologic, and grounded theory. Two of the studies, Morse (1992) and Hawley (2000), described comforting strategies nurses utilize from the perspective of emergency room patients. The results of these independent studies were very similar.

Review of the qualitative nursing literature yields common themes and descriptions of comfort. Themes that emerged describe comfort as multidimensional, unique to the individual, a basic human need, facilitate healing and occurs on a continuum from discomfort to comfort (Hamilton, 1989; Hawley, 2000; Kennedy, 1991; Kolcaba, 1991; McIlveen & Morse, 1995; Morse, 1992; Morse, Bartoff & Hutchinson,

1995, Raines & Morgan, 2000; Williams & Irurita, 2005). Comfort is also described as the act of touching, talking, and listening (Morse, 1992).

Review of the nursing literature produced seven quantitative research studies that incorporated comfort as a variable (Andrews & Chrzanowski, 1990; Butts, 2001; Defner & Bell 2005; Dowd, Kolcaba, & Steiner, 2000; Hogan-Miller, Rustad, Sedelbach & Goldenberg, 1995; Kolcaba & Fox, 1999; Wilson, 2002). Comfort was the dependent variable in five studies (Andrews & Chrzanowski, 1990; Dowd, et al., 2000; Hogan-Miller et al., 1995; Kolcaba & Fox, 1999; Wilson, 2002); defined as a nursing intervention in one study (Butts, 2001); and was considered in relation to other variables in two nursing investigations (Defner & Bell, 2005; Wilson, 2002;).

The literature identifies specific nursing interventions that influence comfort and indicate relationships of comfort to other variables. All seven studies used convenience sampling. Participants in the studies were adults, with three consisting exclusively of women. Two of the investigations, Kolcaba and Fox (1999) and Dowd et al. (2000) used the theoretical framework based on comfort theory put forth by Kolcaba (1994). These studies revealed an increase in comfort in the experimental group over time. Two correlational studies found a significant relationship between comfort and other variables (Butts, 2001; Wilson, 2002). Wilson identified a positive relationship between comfort and perceived nurse caring, and social support; while a negative relationship between emotion focused coping and comfort was realized.

One study by Dowd, Kolcaba and Steiner (2000) measured comfort as the outcome of a cognitive intervention for patients with urinary dysfunction. The authors reported that the treatment group had more comfort and a decrease in urinary symptoms

as compared to a control group. In a subsequent study, comfort was related to bladder function, the patients' perception of bladder health, urinary frequency, and urinary incontinence; as comfort increased urinary symptoms decreased (Dowd, Kolcaba & Steiner, 2002). These two studies identified comfort as a measurable outcome for nursing interventions that address urinary incontinence.

Pelvic Floor Re-education

Pelvic floor re-education is a process that aims to decrease bladder urgency and incontinent episodes using muscle strengthening exercises to teach a person to control their elimination (Aksac et al., 2003; Vickers & Davilla, 2006). Bladder control is learned in early childhood and socially acceptable norms exist for the process of elimination. Pelvic floor re-education attempts to re-establish the continence mechanism.

Review of the literature indicates that pelvic floor re-education with and without biofeedback can often be used in treating women for stress incontinence. Biofeedback is often used by health professionals to help people relax as well as strengthen muscles. It is used successfully in rehabilitating muscles affected by stroke, accidents, surgery and incontinence (Vickers & Davila, 2006).

Biofeedback is often used to assist with pelvic floor re-education in the treatment of stress, urge and mixed urinary incontinence (Vickers & Davila, 2006). Abrams et al. (2002) recommend the use of biofeedback to supply information regarding the performance of pelvic muscle contraction and to facilitate awareness of proprioception, coordination and strength as well as provide motivation to the patient. Initially performance of pelvic floor re-education involves learning the correct muscles to contract and relax. Biofeedback is a useful teaching aid in assisting people to identify these

muscles and perform the exercises properly as well as provide a means of motivation to continue the pelvic muscle exercises between formal sessions (Hiser, 1999).

According to Tries and Eisman (2003) in order for biofeedback therapy to be effective it should include visualization of movements of both the pelvic and abdominal muscles, thus a two channel display is indicated. This is necessary because there is a tendency to contract accessory muscles such as the abdominals and gluteals as a substitute for weak pelvic floor muscles. The aim of biofeedback is to isolate the contraction of the pelvic floor muscles in order to strengthen them. Auditory biofeedback can be substituted if the patient is visually impaired. Muscle activity is measured by electrodes placed on the surface of the skin and/or a sensor placed in the vagina.

Information of the pelvic muscle contraction comes to the patient via visual or auditory feedback. Tries and Eisman (2003) state that the purpose of the biofeedback therapist is to "coach" the patient by encouraging her to watch the signals of relaxing and contracting the pelvic muscles that appear on the screen. As they watch the changes they become aware of the activity of the pelvic muscles and learn to control the muscle reaction to a stressor, i.e. coughing, sneezing (Tries & Eisman). Pelvic floor re-education assisted with biofeedback is a safe and effective treatment modality with no known adverse effects. It does not interfere with other types of treatments for incontinence, such as medication, bladder retraining, diet modifications and surgery (Vickers & Davila, 2006).

A review of the literature indicates that pelvic floor re-education is effective in the treatment of female stress urinary incontinence (Aksac et al., 2003; Aukee et al., 2002; Yoon, Song & Ro, 2003). Sufficient data is not available on use of pelvic floor re-

education with other adjunctive treatments (Bo, Talseth & Holme, 1999; Hay-Smith & Dumoulin, 2005). A number of studies compared pelvic floor re-education with and without biofeedback for treatment of stress urinary incontinence (Bond et al. 2004; Burgio et al. 2002; Dattillo, 2001; Kegel, 1948). A landmark study by Arnold Kegel (1948) reported a successful outcome in women performing pelvic muscle exercises using a perineometer as a biofeedback apparatus. Kegel used biofeedback to improve motivation of the individual and to encourage a sustained effort during each contraction. Kegel recommends the performance of pelvic exercise prior to gynecologic surgery.

Study outcomes comparing pelvic floor re-education alone and with biofeedback emphasize that correct identification of pelvic floor muscles is related to successful therapy (Aukee, et al., 2002; Vickers & Davila, 2006). Vickers and Davila state that both treatments will reduce the severity of incontinence. However, patients using biofeedback have a stronger muscle contraction, more endurance, and a more rapid decrease in incontinence episodes.

On the other hand, although pelvic floor re-education is effective in treating stress urinary incontinence a review of the literature by Morkved, Bo, and Fjortoft (2002) showed no statistically significant difference in the effect of pelvic floor re-education with and without biofeedback. In this review the authors suggest that using biofeedback during training may motivate women and should remain an option in clinical settings.

Pelvic floor re-education appears to be an effective first-line treatment strategy for women with stress, urge and mixed urinary incontinence (Aukee et al., 2002; Burgio et al., 2002; Dattilo, 2001; Doughterty et al., 2002; Glavind, 2001; Hayn, Greco, Capuano & Byrnes, 2000; Kegel, 1948; Smith, Boileau & Buan, 2000). Outcomes from studies

comparing pelvic floor re-education alone to pelvic floor re-education assisted with biofeedback emphasize that correctly identifying the pelvic floor muscles is directly related to successful therapy (Abrams et al., 2002). Burgio et al. report that both strategies will significantly reduce the frequency and amount of incontinence.

The evidence presented in the literature does not fully support the hypothesis that pelvic floor re-education with biofeedback is more effective than pelvic floor re-education alone. However, patients who undergo biofeedback assisted therapy have a stronger muscle contraction and more rapid reduction of leakage episodes (Pages, Jahr, Schaufele, & Eberhard, 2001). Biofeedback is effective in helping patients correctly identify the pelvic muscles and can improve outcomes by providing motivation (Vickers & Davila, 2006).

Review of the literature revealed one study, (Jarvis, Hallam, Lujic, Abbott & Vancaille, 2005) that investigated the role of pelvic floor re-education in women having surgery for pelvic organ prolapse and urinary incontinence. However, this study excluded women having the pubovaginal sling TVT™ procedure. The study used the paper towel test and reported no significant difference in stress incontinence leakage between groups following surgery (Jarvis et al). However, there was a significant difference between groups in the urinary symptom specific health and quality of life questionnaire. The quality of life scores showed a statistically significant improvement in the women in the treatment group while the control group did not achieve a statistical significant improvement following surgery. The researchers propose that women who receive pelvic muscle re-education prior to pelvic surgery seem to understand the role of the pelvic floor

in maintaining continence and demonstrate an increase in muscle strength with improved bladder capacity and proper voiding function.

Integrity of the continence mechanism is dependent on the state of the bladder, urethra, and rectum along with the supporting structures of the levator ani muscles, and the endo-pelvic fascia and ligaments (Abrams et al., 2002). Thus the state of incontinence is amenable to improvement through pelvic muscle exercise. Pelvic floor muscle re-education in the treatment of urinary incontinence is guided by the principles of exercise physiology that consists of specificity, overload and reversibility (Johnson, 2001). The striated muscles of the pelvic floor include both type II (fast twitch), and type I (slow twitch) fibers. Types I, slow twitch, fibers close the urethra in order to maintain continence through a sustained contraction over a long period of time. On the other hand, the fast twitch, type II fibers provide strong, quick muscle contractions in times of increased intra abdominal pressure but are easily fatigued (Tries & Eisman, 2003).

According to Johnson (2001) specificity includes selecting low intensity exercises that are targeted to increase stamina and work to increase the endurance of the of the easily fatigued fast twitch type II fibers. In addition to specificity, overload is achieved by exposing the muscle to greater than normal effort to increase its functional and structural capacity. This ‘load’ must be increased in order to sustain improvement of the muscle (Johnson). Finally, reversibility describes the loss of strength and endurance when exercise and training are discontinued (Johnson).

Johnson (2001) recommends selecting an exercise training program according to the desired activity of the muscle group. Muscle strength and endurance are both important in treatment protocols for stress urinary incontinence and both were addressed

during this pelvic floor re-education intervention. Strength maintains the position of the bladder neck during daily activities while endurance provides recruitment of the type II fibers in times of increased intra abdominal pressure.

A meta-analysis of pelvic floor muscle training by Choi, Palmer and Park (2007) reported that analysis by age suggests that the effect of a pelvic muscle exercise treatment is greater in younger women as compared to older age groups. However, pelvic floor muscle training was significantly effective in reducing incontinence episodes in both groups. Thus, age should not be a disqualifying factor as older women can benefit from pelvic muscle exercise training.

Following surgery strong pelvic muscles are useful to facilitate the healing process, assist in efforts to suppress leakage and urgency, and afford the patient the ability to relax the pelvic floor during bladder emptying (Johnson, 2001; Kegel, 1948; Tries & Eisman, 2003).

Summary

In summary, review of the literature reveals that stress urinary incontinence in women is a complex problem that warrants multiple approaches to evaluation and treatment strategies. It is significant to nursing because it affects a large number of women, has a high economic cost and interferes with social encounters.

Review of the literature confirms that surgery and pelvic floor re-education are effective treatment strategies for this condition. Based on review of the literature a pelvic floor re-education intervention prior to surgery will potentially prepare patients preoperatively through information and physical exercise thereby decreasing post

operative complications associated with discomfort and bladder dysfunction, resulting in dissatisfaction with surgical outcomes.

Comfort is a concept that is sufficiently defined for nursing research and has been used in the framework of comfort theory to measure the effectiveness of nursing interventions. Therefore, review of the literature supports comfort as a measurement outcome of a pelvic floor re-education intervention directed toward female stress urinary incontinence.

CHAPTER 3: DESIGN AND METHODOLOGY

Overall Approach and Rationale

This was a preliminary exploratory study using a quasi-experimental mixed model design. Women scheduled to have corrective surgery for stress urinary incontinence were randomly assigned to the control or treatment group. The treatment group participated in a pelvic floor re-education intervention and was compared to the control group that did not receive the pelvic floor re-education intervention. This type of design determines whether there are significant between group differences as well as within subjects' effect over time on the dependent variables (comfort and stress urinary incontinence).

Following the intervention the participants in the treatment group were asked if it was difficult to attend the training sessions and were the sessions helpful (Appendix E) in order to assess the feasibility of this intervention as a possible treatment strategy.

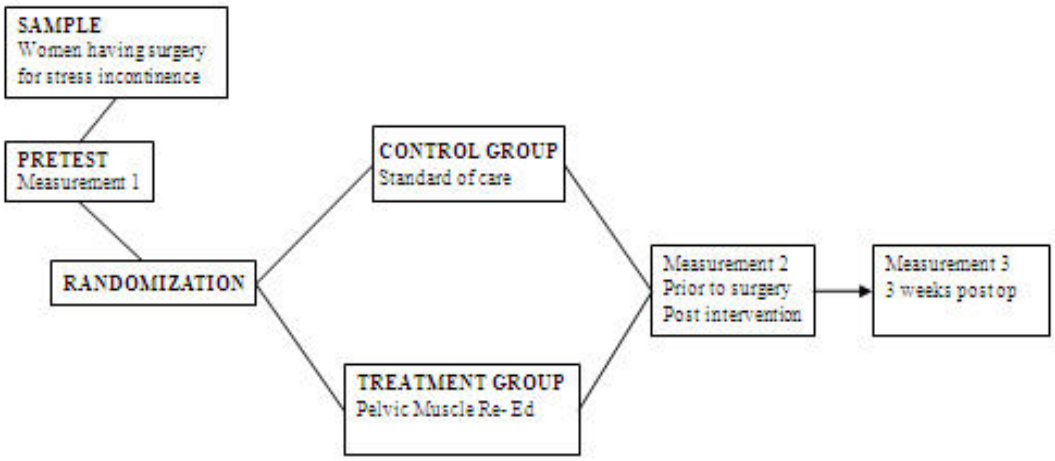

Figure 2 Mixed Model Protocol

Site Selection

The research site was an ambulatory women's health center at a major teaching hospital in central New Jersey. The center, under the direction of a fellowship trained,

board certified urogynecologist provides a comprehensive treatment and evaluation program for women with urinary incontinence and pelvic organ prolapse. Approximately ninety patients with a complaint of urinary incontinence are seen each week at the office with approximately eight to ten of these having surgery for stress urinary incontinence. This volume of patients with the diagnosis of stress urinary incontinence and the surgeon's willingness to be involved in this study, made it possible to recruit participants for the study. The hospital administration granted permission for the researcher to volunteer her time and use the available biofeedback equipment to conduct the intervention.

Population Sample

The sample size required for this study was guided by a power analysis using the software program G*Power (Version 3.0.10, Dusseldorf, Germany). The power analysis was based on a mixed model (Group x Time) analysis of variance (ANOVA) where two groups (Control and Intervention) were to be compared at three time periods for the primary dependent variable: comfort. Since the primary interest was the outcome of the interaction between the groups and time, a medium effect size (.25) for the interaction effect was postulated in keeping with Cohen's (1992) recommendation for a standardized effect size for an F distribution (*Cohen's* f^2). An effect size is considered to be the smallest immediate effect that is clinically meaningful in the target population for the outcome measures. Power was set to .80, meaning there would be an 80% probability of reaching statistical significance if there is difference between the groups.

In this study, for a significance level of alpha = .05, with a medium effect size of .25, to achieve a power of .80, a total sample size of 28 subjects with 14 in each group

was required. Attrition rate was calculated based on similar studies by Jarvis et al. 2005, Dowd, Kolcaba and Steiner, 2000 and Davis et al., 2004. A range of 4 to 10 patients did not complete these studies mainly because of cancellation of surgery or lost to long term follow-up.

Twenty-nine female subjects with a diagnosis of stress urinary incontinence opting for surgical correction were recruited for the study. Women were notified of the study through an announcement flyer placed in the waiting room and in the bathrooms. Those interested contacted the researcher through the office telephone number or by request through the office staff. After approval from the IRB at the respective institutions, Saint Peter's University Hospital and Drexel University, the researcher obtained informed consent from the women interested in participating in the study.

Criteria for inclusion in the study were adult women (age $\geq$ 35-80) who have a diagnosis of stress urinary incontinence, confirmed by urodynamic studies, and are scheduled for corrective surgery; those women undergoing concomitant surgical procedures were also eligible. Concomitant surgical procedures included repair of pelvic organ prolapse (bladder, rectum and/or uterus).

The subjects were required to follow written and verbal instructions in English and return for evaluation at two to four weeks post-operatively. This is the usual first post operative visit in this practice setting. Those women randomized to the intervention group were required to attend the two pelvic floor re-education sessions.

Exclusion criteria included: women <35 and >80 years old; those that do not speak, read, write and understand the English language; and women who have

neuromuscular conditions affecting their incontinence (i.e., leg paralysis, multiple sclerosis, Parkinson's disease).

Methods

Subjects were initially screened for inclusion criteria after they contacted the investigator and showed an interest in the study. At the first meeting, the investigator described the study, answered questions and reviewed the informed consent form with the subjects. After informed consent, but prior to randomization, the subjects were assessed for stress urinary incontinence using the paper towel test and filled out the Demographic Data Sheet (Appendix C) and Urinary Incontinence Frequency and Comfort Questionnaire (measurement 1). Subjects then were randomized into the control and experimental groups. Random assignment was made by using sealed envelopes; 15 containing a Group A (control group) ticket and 15 containing a Group B (experimental group) ticket. These 30 sealed plain envelopes were placed in a bag mixed and hand picked.

Each subject in the experimental group attended two pelvic floor re-education sessions provided by the researcher. These sessions were given privately to the individual patient; session 1, approximately 4-6 weeks prior to the surgery and session 2, 1-2 weeks after session 1. Each session was approximately 60 minutes. Session 1 included: education of basic bladder health (10 minutes). Models of the pelvis and pictures were used by the researcher to demonstrate anatomy and location of pelvic organs and muscles along with the rationale and explanation of performing 'Kegel' exercises using biofeedback. Participants were given instruction on fluid management (drink 6-8 glasses of non-caffeinated fluid throughout the day; eliminate or gradually decrease caffeine and

aspartame). Instruction on relaxed breathing were given and the breathing was practiced (5 minutes); this exercise consists of slow relaxed breathing- inhale then exhale-and subjects were instructed to maintain this breathing pattern throughout the performance of the exercise. The subject was given and instructed on insertion and cleaning of the vaginal sensor for the biofeedback and then attached to the SRS biofeedback system. The sensors were purchased by the researcher and given to the subjects for individual use. The subject kept the sensor and brought it with her to the subsequent visit. The subject then practiced a series of pelvic muscle exercises, using the beyond Kegel protocol of the SRS biofeedback system, consisting of quick contractions and contract and hold for10 seconds and relax for 10 seconds (30-35 minutes). At the completion of the exercise segment, the subject was given instruction for home practice and a chance to ask questions (10-15 minutes).

The second session was a reinforcement of information given at session one (10 minutes), practice of pelvic muscle exercises using biofeedback (30-40 minutes) review of post-operative instructions and a chance to ask questions (10-15 minutes). At each session the patient was given a home program of pelvic exercises to do.

The control group did not participate in the sessions. However, because of ethical considerations the control group was provided with the usual pre and postoperative support, factual information regarding their surgery and was given accurate answers to specific questions. Pamphlets that are available at the office were equally distributed to both groups, along with the usual post operative and discharge instructions which are the standard of care for this diagnosis and surgical treatment.

The effect of pelvic floor re-education on comfort and stress urinary incontinence was measured three times: measurement 1 took place following informed consent and prior to randomization; the subject was observed for urine leaks using the paper towel test. Following completion of the test the results were recorded as positive or negative, and quantified by measurement of the wet spot on the towel and converted to milliliters using the look-up table. After completion of the paper towel test the subject was asked to fill out the UIFCQ. Measurement 2, (paper towel test and UIFCQ) was collected following the intervention but before the surgery (1-3 weeks prior; during the meeting with the surgeon to sign consent for surgery); the final measurement 3, (paper towel test and UIFCQ) was taken at approximately 3 weeks (+ or – 2 weeks) post operative (the usual follow up visit). For each measurement the participants performed the 'paper towel test' and filled out the UIFCQ. After each measurement the urine leak was quantified and the comfort score was tallied by the investigator. Two qualitative questions (Appendix D) were asked of all subjects who completed the study and were in the experimental group. Did you find it difficult to attend all the sessions? If yes, what could be changed to make it easier to attend the sessions? Did you find the sessions helpful? Additional comments were encouraged.

In order to make it most convenient for the patients to participate in the study and to decrease attrition, the usual time frame for scheduling surgery in this practice was considered in determining the study protocol. There is a usual time period of six to eight weeks from decision to have surgery to actual surgery date. The decision to limit the pelvic floor re-education to two sessions was based on this time constraint, and review of the literature.

Gilbey et al. (2003) required patients to attend two supervised exercise sessions, in conjunction with a home program prior to hip arthroplasty surgery. In a study by Bond et al. (2004) patients often required only three pelvic floor re-education sessions for treating stress urinary incontinence, with the first session consisting of a history and physical exam. In addition, Choi, Palmer and Park (2007) recommended a home program of pelvic muscle exercise to include three sets of 8 – 12 repetitions carried out on "most" days.

Reliability and Validity

Demographic information was collected from the medical record and through inquiry of the subjects. This information included: age, ethnicity, parity, weight, marital status, socio-economic status, education level, and concomitant surgery.

Paper towel test for stress urinary incontinence

For the purpose of this investigation stress urinary incontinence was operationalized using the paper towel test that was developed by Miller, Ashton-Miller, and Delancey (1998) and used in the study by Jarvis et al. (2005) to quantify urinary leaks. At the three time period measures, the participants were asked to come to the clinic with a full bladder. Participants were instructed not to void for at least two hours before their appointment and to drink two eight-ounce glasses of fluid one hour before testing. Miller et al. state that by following this protocol most women can achieve a voiding volume between 150 and 350ccs. This expected volume provides enough urine in the bladder to conduct the test. While standing, the patient was asked to dry the perineum and place a sanitary pad covered by a paper towel in her panties. She then was instructed to cough three times deeply. This was repeated three times with a ten second rest between

sets. The test was recorded as positive for stress incontinence, wetness is observed on the paper towel, or negative for stress incontinence, no wetness is observed on the paper towel. In addition, the paper towel was assessed to quantify stress-related urinary leaks. Wetness on the paper towel was sized by measuring the length and width of the wetted area at its largest points, and using a table to estimate the corresponding leakage volume. Four bench tests were performed by Miller et al. which demonstrated that an average of $25.4cm^2$ was equal to each 1ml of fluid volume. A test-retest reliability of the method of quantification was evaluated with a sample of 8 women; 95% of within and across visit comparison of urine loss were within 1ml.

Urinary Incontinence Frequency and Comfort Questionnaire (UIFCQ)

Comfort was defined as a holistic outcome associated with the ease, relief and transcendence of the stressor, stress urinary incontinence. It was measured at the three time periods by the Urinary Incontinence and Frequency Comfort Questionnaire which consists of 27 statements specific to feelings associated with living with urinary incontinence (Dowd et al., 2000). The items in the UIFCQ are related to the four contexts of comfort and provide a holistic measure of comfort (Dowd, Kolcaba, & Steiner, 2002). The tool is formatted using a Likert-type score ranging from strongly agree (6) to strongly disagree (1); scores range from the highest possible score (162) to lowest possible score (27). Higher scores indicate a higher level of comfort.

Cronbach's alpha for this instrument averaged 0.82 over four measurements in a study conducted by Dowd, et al. (2000) which indicates acceptable reliability. The psychometric properties of this instrument were tested again by Dowd et al. with Cronbach's alpha for internal consistency reliability .74 at time 1 and .83 at time 2.

Internal consistency (Cronbach's alpha) in the current study of the items that were summed to derive the total comfort score on the UIFCQ showed good internal consistency reliability for the comfort scale during baseline (.84) and post surgery (.90) and adequate reliability following post pelvic floor exercise intervention (.63).

Validity for this instrument was assessed by correlating the UIFCQ with established measures of urinary incontinence (Dowd et al. 2002). Correlations of measures at time 1 and 2 revealed statistically significant results ($p < .001$) when compared with Incontinence Impact Questionnaire (IIQ), Compromised Urinary Bladder Symptoms (CUBS) and Bladder Function Questionnaire (BFQ) (Dowd et al., 2002).

Data Collection

The investigator obtained consent from all subjects and collected and managed all data. Data was coded anonymously. Only code numbers can be tracked to subjects and a code log was kept in a private office in a locked file cabinet, accessible only to the investigator.

The investigator was aware that bias is a consideration that can influence the results of the study. According to Polit and Beck (2008) the researcher's subjectivity can misrepresent information or communicate expectations to the subjects. Masking is a method that can enhance objectivity of the study. However, because of ethical considerations with informed consent this study was an open study.

In this study, the researcher adhered strictly to the study protocol in order convey the same information to each subject and to decrease the possibility of bias through *flawed implementation* (Polit & Beck). Randomly assigning subjects to the control and experimental groups helped to avoid systematic bias in the composition of the groups

(Polit & Beck). Another tool for managing bias is to control for confounding variables that can affect the dependent variable. A pre-test, post-test design and measurement before randomization also helped control for bias.

Role of the Researcher

According to Burns and Grove (2007) the role of researchers is dependent on their expertise, knowledge and experience with the problem under investigation. The research team for this study consisted of the following members: Investigators: Joan E. Zaccardi, MS, APRN, BC, a Family Nurse Practitioner, with expertise in women's health and experience in pelvic floor re-education including biofeedback; Linda Wilson, RN, PhD, CPAN, CAPA, BC, CNE, Assistant Professor at Drexel University, who has clinical and research experience in pain and comfort, and Mark Mokrzycki, MD, a Board Certified Physician in Obstetrics and Gynecology, who is Director of Urogynecology Arts of New Jersey and Associate Professor of OB/GYN at Drexel University College of Medicine. Consultants for the study were: Barbara Celia, BSN, MSN, EdD, Clinical Assistant Professor at Drexel University who has experience, publications and national presentations on research topics related to pain management and Kim Noble, RN, PhD, CPAN, Assistant Professor at Temple University College of Health Professionals who holds a Doctorate of Philosophy in Physiology and has clinical experience in pain management.

The primary investigator in this study was responsible for informed consent of all participants and adherence to the study protocol as set forth by the Committee for the Protection of Human Subjects. In addition the researcher maintained confidentiality of all participants and was available to the participants to answer questions related to the study.

Data Analysis

The primary statistical analysis of the research hypotheses (H_1= comfort scores will increase across time and amount of urine leaks will decrease across time in women having surgery for stress urinary incontinence; H_2 = women in the pelvic floor re-education intervention group will have greater comfort as compared to women in the control group who do not have the pelvic floor re-education intervention; and H_3 = women in the pelvic floor re-education intervention group will have less stress incontinence as compared to women in the control group who do not have the pelvic floor re-education intervention) was the mixed model analysis of variance (ANOVA). The basic assumptions of normality of distribution of the dependent variables, assumption of sphericity, and independence of scores between participants should be met for mixed model ANOVA (Munro, 2005).

According to Polit and Beck (2008) one situation in which this test is appropriate is when there are three or more measures of the same dependent variable for each subject and/or two or more measurements of the dependent variable between two or more groups. In this study the dependent variable was measured at 3 time points in the control and experimental group: baseline, following the intervention and following surgery. Mixed model ANOVA analysis results between groups (the control and the experimental group) as well as determines within subject results (each subject is measured three times on the same variable). Comparing the control and experimental groups tells us if the intervention had an effect on the outcome. On the other hand, the within subject measure answers the question, is there an effect over time? An F-test “main effect for time,” was computed to see if the dependent variable changed over time. This statistic is not

dependent on the group but rather calculates the marginal means across both groups at each time point. An F-test for group **"**the main effect for group" evaluated if the dependent variable changed between the groups, without regard to time (Tabachnick & Fidell, 2006). Post hoc comparison was conducted once a significant effect was obtained to compare the different time points and determine whether the dependent variable changed between any two time points. The third F-test is referred to as the "group x time interaction" and evaluates if the dependent variables changes across time and across groups (Tabachnick & Fidell, 2006). Qualitative questions were analyzed using descriptive statistics.

Protection of Human Subjects

The human subjects in this study are not considered a vulnerable research group. However confidentiality regarding the subject's identity and medical information was strictly maintained. The protection of human subjects is outlined in the consent form (Appendix E).

Once the participants were interested in the study an appointment was arranged for a meeting. During the meeting the purpose and objectives of the study as well as the responsibilities of the participant and the researcher was disclosed. Interested participants were given a chance to read the consent form in a private room, be given a verbal explanation of all information and encouraged to ask questions. Participants signed the consent form and received a copy of the signed form for their personal records. If the participant qualified for the study based on the inclusion and exclusion criteria, a subject number was assigned. Identifying information of names, telephone numbers, email address, and study number was kept separate from the data and accessed only by the

investigator. A hard copy of this information was kept in a locked file cabinet in the private office of the investigator. Data collected during the study was identified only by the subject number and kept secure by the investigator, separate from the identifying information.

Risks to subjects participating in this study were minimal. That is, the probability of adverse consequences, harm or discomfort are not more than those encountered in daily life or in the performance of routine evaluations for urinary incontinence. A review of the literature of pelvic floor re-education as a treatment strategy for urinary incontinence reveals no reported serious adverse effects (Hay-Smith & Dumoulin, 2005). According to Davila, Ghoniem and Wexner (2006) Pelvic floor re-education is an attractive conservative treatment option because it is cost effective, noninvasive, easily tolerated, morbidity free, and does not interfere with any future treatment options. G. W. Davila (personal communication, June 20, 2007) stated that he would not expect a negative impact from a pelvic floor re-education intervention in patients having corrective surgery for urinary incontinence. At the Cleveland Clinic in Florida pelvic floor re-education is routinely used as a first line therapy for many conditions including patients having surgery for stress urinary incontinence (Davila et al., 2006).

The Cochrane review of the literature regarding pelvic floor re-education in the management of female urinary incontinence included analysis of six trials involving 403 women and reported no adverse events occurring in the intervention groups (Hay-Smith & Dumoulin, 2005). Bo, Talseth and Holme (1999) report that two women withdrew from the exercise group during the study, one because of lack of motivation and the other because of the time it took to travel to the training session. Lagro-Janssen, Debruyne,

Smits and Van Wheel (1992) reported a complaint of pain by one subject, feelings of discomfort while performing the exercise were reported by three participants, and two complained of being bothered by having to perform the exercise. These complaints were temporary.

The biofeedback vaginal sensor used during the pelvic floor re-education intervention may cause a feeling of pressure or discomfort for some subjects with a potential for vaginal irritation and temporary pain. There may be risks and discomforts that are not yet known. If a participant experienced any adverse effects the need for discontinuation of the intervention was at the discretion of the patient and researcher and/or physician.

The subjects' participation in the study was entirely voluntary and this was stated in the informed consent and verbally communicated by the investigator. The participants could decide not to participate in the study or withdraw from the study at any time, without penalty or loss of benefits to which they are entitled. The participants may call the investigator at anytime with questions regarding the study. For health related questions falling outside the scope of practice of professional nursing in the states of New Jersey and Pennsylvania, the subjects were referred to the physician performing the surgery.

All participants who completed the study (attended both sessions and completed all measurements) received a $25.00 gift card to Target. In addition, the participants in the experimental group received complimentary parking ($3.00/visit) for attending the pelvic floor re-education sessions.

CHAPTER 4: RESULTS

Overview

The purpose of this study was twofold: to examine the effect of a pelvic floor re-education intervention on comfort and stress urinary incontinence in women having corrective surgery and to determine the feasibility of a larger parent study. Mixed model (Group x Time) ANOVAs were used to analyze differences between the control and intervention groups for comfort scores and paper towel test urinary leak scores. This analysis was employed to determine: 1) if the two groups significantly differed in comfort and stress incontinence measures after the intervention 2) to evaluate if the two groups have a significant difference in comfort and stress incontinence across the three time points and 3) to determine if there is an interaction between group and time on comfort scores and urinary leak scores.

Time was the within-subjects (repeated) measure and was evaluated at three time points: (1) at baseline (prior to randomization) (2) before surgery at the pre-operative visit (after the intervention in the treatment group) and (3) at the post operative office visit examination. Data on comfort was collected from the 28 women participating in the study using the Urinary Incontinence and Frequency Comfort Questionnaire (UIFQ). Stress urinary incontinence was observed and quantified with the paper towel test. In addition, those women who received the pelvic floor re-education treatment were asked if they considered the intervention helpful and if they found it inconvenient to attend the treatment sessions. An alpha level of .05 was used for all statistical analysis. Results of statistical analysis performed on the data are presented in this chapter.

Subject Demographics

A sample of 29 women who met the delimitations of the study were recruited and enrolled. Twenty-eight completed all the required outcome measures. One subject did not complete the study as she deferred her surgery and therefore was not counted in the data analysis (J. F. Glutting, personal communication, August 8, 2007). All participants had a diagnosis of stress urinary incontinence that was confirmed by urodynamic studies prior to scheduling surgery. Participant demographics for this study are summarized in Table 1. Of the 28 women who completed the study, the majority of participants were Caucasian (79%); married (76%); with 55% reporting an annual income of over $75,000, 72% had the pubovaginal sling procedure with repair of pelvic organ prolapse and 29% had sling only. Participants were between 39 to 75 years (M = 54, SD = 8.0) of age. Weight of the participants ranged from 122 lbs to 250 lbs (M = 168, SD = 28.6). Range of number of children was 0-4 (M = 2, SD = .9). All participants were high school graduates, with 41% reporting a Bachelor degree; 24% had completed some college credits, and the remainder reported an Associate degree (17%) or Graduate degree (10%).

Table 1 Frequency Distribution of Demographic Variables

Characteristic	Mean	Standard Deviation
Age	54 years	8.0
Weight	168 lbs	28.6
Number of Children	2	.9

Table 1 (*continued*)

Characteristic		N	Percentage
Race	Caucasian	22	79
	African American	2	7
	Latino	2	7
	Asian	1	3
	Other	1	1
Marital Status	Married	21	76
	Single	2	7
	Widow	2	10
	Divorced	3	7
Education Level			
	High School Diploma	2	7
	Some College	6	24
	Associate Degree	5	17
	Baccalaureate Degree	12	41
	Masters Degree	2	7
	Professional/Doctorate	1	3
Income	$10,000 – $30,000	2	6
	$31,000 - $50,000	5	17
	$51,000 – $75,000	5	17
	> $75,000	16	55
Type of Surgery			
	Pubovaginal Sling TVT™	8	29
	Sling plus prolapse repair	20	72

Differences of demographic variables were analyzed to examine similarity between the control and experimental groups. T-tests results revealed that the groups were not significantly different in age (p=.54), weight (p=.28), number of children (p=.39) and type of surgery (p = .22). Chi square tests demonstrated no difference between groups regarding race (p = .36), marital status (p=.92), and education (p = .54). However, there was a significant difference in the income level of the groups (p = .03). This difference did not impact the results as all participants received the same level of care and intervention treatment, provided by the same practitioner regardless of income level.

Data was analyzed to test if it met the assumptions of a mixed model ANOVA, namely normality of distribution of the dependent variables and the assumption of sphericity. Data collected from the comfort questionnaire was normally distributed; however the Mauchly's test of sphericity was significant indicating that the assumption of shericity was violated. A Greenhouse-Geisser correction to the degrees of freedom was made to account for the violation of this assumption. Similar results were obtained with the paper towel test urinary leak measurement. The data was normally distributed but the sphericity assumption was violated. Thus, a Greenhouse-Geisser correction was made to account for this violation.

Research Questions One and Two

To answer the first and second research questions: "Is there an effect of time on comfort and urine leaks in women having surgery for stress incontinence?" and "Is there an effect of a pelvic floor re-education intervention on comfort in women having incontinence surgery?" results from the Greenhouse-Geisser corrected mixed model

ANOVA for differences in comfort scores revealed that only the main effect of time was significant F (1.46, 37.94) = 35.68, p = .001, η = .76, power 1.0 (see Figure 3).

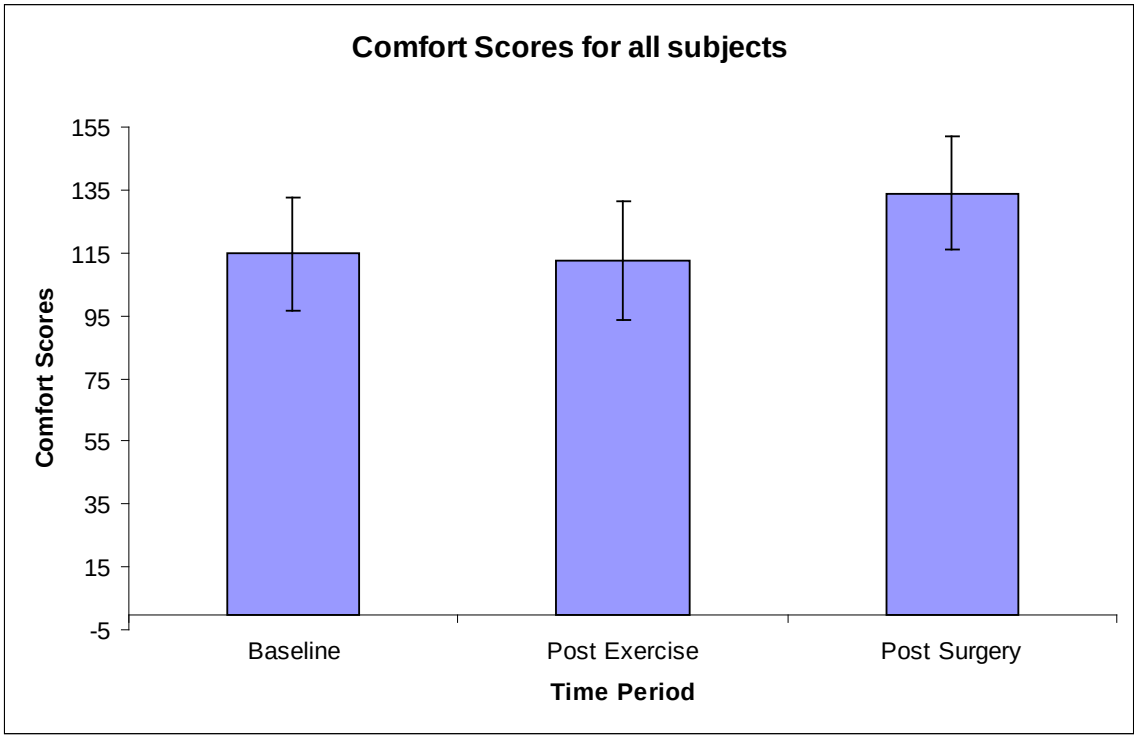

Figure 3 Comfort Scores All Subjects

No statistically significant differences were found for the main effect of group, F (1, 26) = 1.27, p = .27, η = .22, power = .19 or for the interaction between group and time F (1.46, 37.94) = .470, p = .569, η = .13, power = .11. Post hoc testing revealed that comfort scores were statistically significant between time periods two and three (p = .028). The effect size of the main effect of time was a much larger than typical effect, whereas a medium effect was noted for the main effect of group (Cohen, 1992). The effect size for the group by time interaction was small (Cohen, 1992). Table 2 presents the means and standard deviation of comfort scores at three specified time measurements of the two groups (A = control group and B = experimental group). Mean comfort scores were higher over time in both groups (Figure 4).

Table 2 Means and Standard Deviations for Comfort Score by Group and Time

Time	Group	Mean	Standard Deviation	N
Time 1	A	112.8	16.6	15
	B	116.7	20.5	13
	Total	114.6	18.2	28
Time 2	A	108.2	19.7	15
	B	117.3	17.0	13
	Total	112.4	18.8	28
Time 3	A	130.3	18.8	15
	B	138.9	16.9	13
	Total	133.8	18.1	28

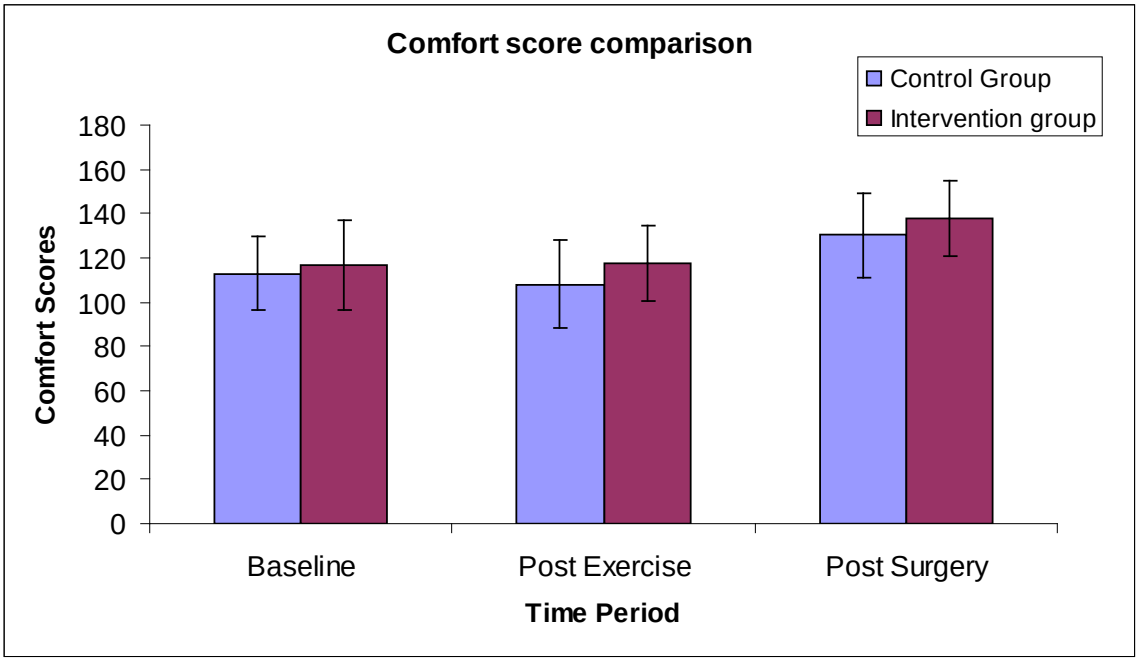

Figure 4 Comfort Score Comparison

Following a Greenhouse-Geisser correction, results from the mixed model ANOVA for differences in amount of urinary leaks revealed no statistically significant

differences for the main effect of time F(1.39, 37.57) = 1.66, p = .20, η = .24, power = .28 (Figure 5).

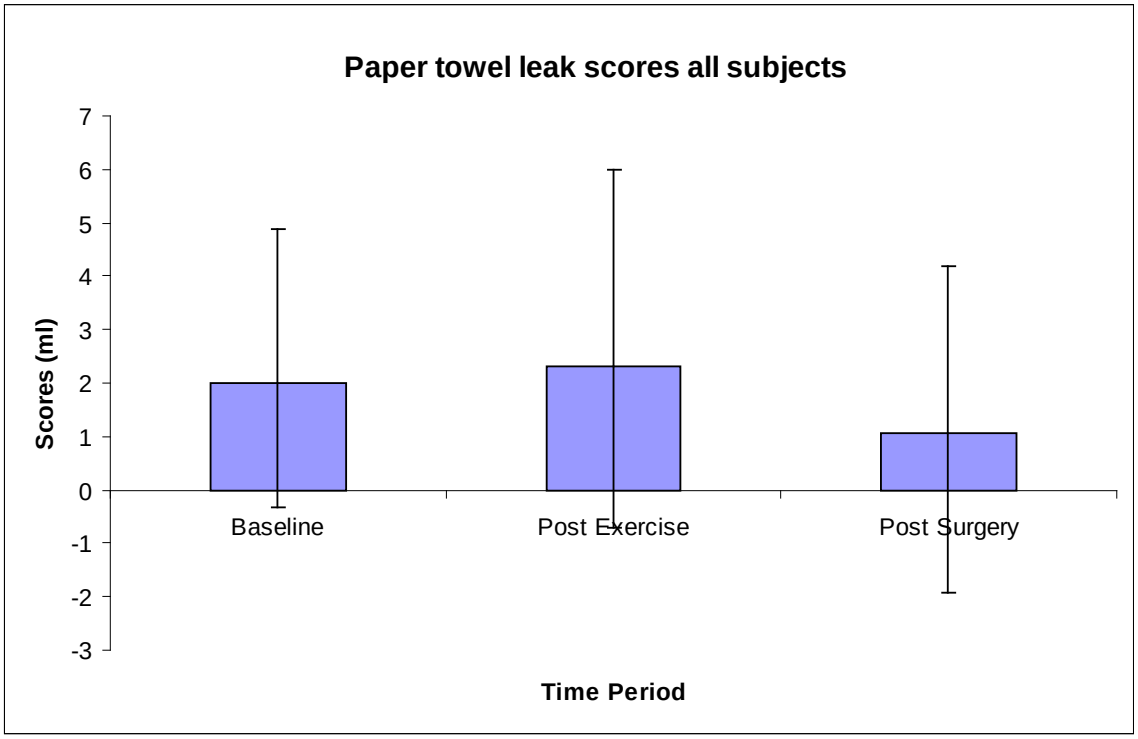

Figure 5 Paper Towel Leak Scores for All Subjects

Results for the main effect of group were not statistically significant, F (1, 26) = .327, p = .57, η = .11, power = .09, and no statistically significant differences for the interaction between group and time were found, F (1.39, 37.57) = 1.46, p = .24, η = .23, power equals .09 (Figure 6).

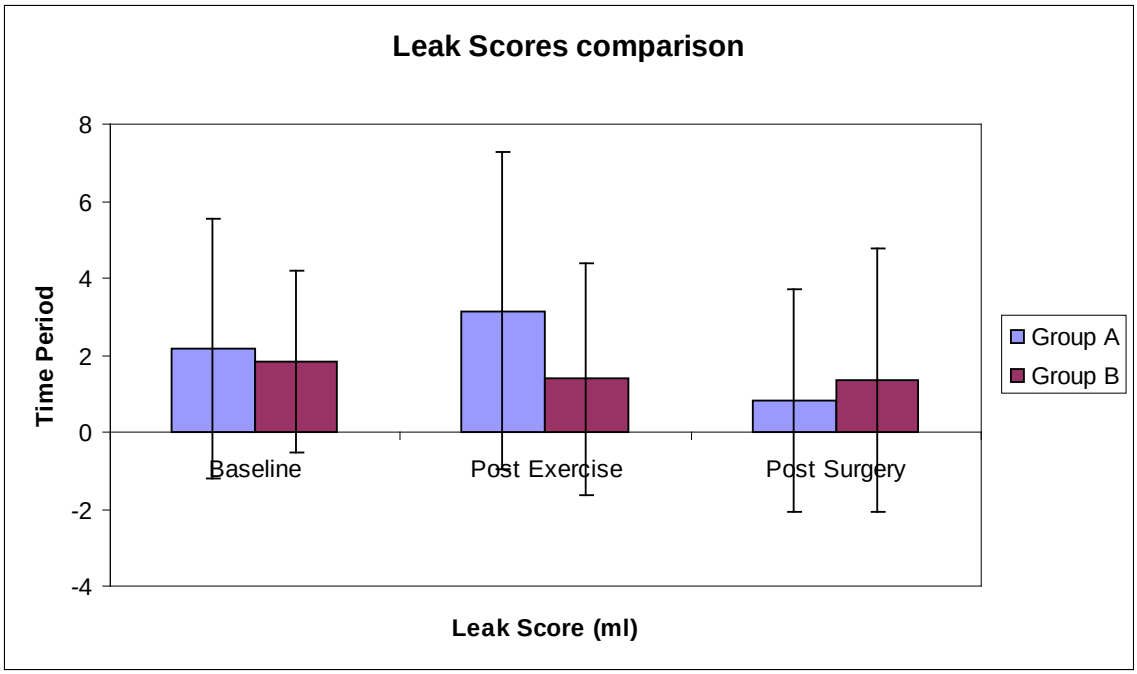

Figure 6 Group Comparisons for Paper Towel Leak Scores

The effect size for the main effect of time shows a medium effect (Cohen, 1992), while the effect size for the main effect of group is small (Cohen, 1992). The effect size for the interaction for group and time was medium (Cohen, 1992). The means and standard deviation of urinary leaks at three specified time measurements of the two groups (A = control group and B = experimental group) are depicted in Table 3.

Table 3 Means and Standard Deviation for Urinary Leaks by Group and Time

Time	Group	Mean (mls)	Standard Deviation	N
Time 1				
	A	2.2	3.4	15
	B	1.8	2.4	13
	Total	2.0	2.9	28
Time 2				
	A	3.2	4.1	15
	B	1.4	3.0	13
	Total	2.3	3.7	28
Time 3				
	A	.8	2.9	15
	B	1.4	3.4	13
	Total	1.1	3.1	28

Following the final measurement of comfort and urine leaks at the post operative visit, the women in the experimental group responded to two feasibility questions 1) Did you find it difficult to attend the two biofeedback sessions? Thirteen (100%) of respondents answered “no”; 2) did you find the sessions helpful? Again 13 (100%) responded yes. Comments offered by the participants are as follows: 7 (54%) felt they learned to do the Kegel exercises correctly; 6 (46%) found that they were better prepared for the surgery; 2 (15%) did not offer any additional comments; 1(8%) said she would continue to do the pelvic muscle exercises after the surgery.

CHAPTER 5: SUMMARY AND INDICATIONS FOR FUTURE RESEACH

Overview of the Study

Female stress urinary incontinence continues to be an important women's health issue because it affects many aspects of social interactions, interferes with exercise and activities of daily living, is often a cause of discomfort and irritation, and can lead to adverse health consequences. Review of the literature discloses previous research that has encompassed qualitative and quantitative studies directed at understanding treatment options and evaluating outcomes with both subjective and objective measures.

Pelvic muscle re-education and surgical correction are both cited in the literature as effective treatment strategies for stress urinary incontinence. However, limited information is available for treatment of this condition with both modalities. No studies were found that incorporated comfort as an outcome measure with a pelvic floor re-education intervention on women who had a pubovaginal sling (TVT™) for stress urinary incontinence.

The purpose of this study was to examine the effect of a pelvic floor re-education intervention on comfort and stress urinary incontinence in women opting for surgical correction and to explore the patient's feelings regarding the ease and benefit of attending the pelvic floor re-education intervention. In addition, results from this study will be used to determine if a full study is warranted. Due to limited availability of subjects, equipment, and financing, a preliminary exploratory study was undertaken. This study sought to fill a gap in nursing research which has not investigated the benefit of combining these treatment options.

The assumption of this study was that women who received the intervention would fare better in comfort scores and show a decrease in stress urinary incontinence leaks prior to the surgery (after attending the pelvic floor re-education training) and following surgery (at the usual post operative visit) than the women in the control group who did not have the intervention.

Comfort Theory (Kolcaba, 1994) was employed as a basis for inquiry into the effect of a pelvic floor re-education intervention on the dependent variables, comfort and stress urinary incontinence. In accordance with the conceptual framework of Comfort Theory (Kolcaba), this study focused on comfort as the outcome of a pelvic floor re-education intervention and this outcome was measured by both subjective and objective patient perspectives.

This chapter will discuss the results and interpret the findings in relation to the research questions, Comfort Theory, hypotheses and review of the current literature.

Conclusions

Hypothesis One

Hypothesis 1 stated that comfort scores would increase across time and amount of urine leaks would decrease across time in women having surgery for stress urinary incontinence. Comfort was the primary outcome variable in this study and was defined as meeting the patients' needs for relief, ease, or transcendence occurring in stressful healthcare situations (Kolcaba, 1994).

The first part of the hypothesis was supported as results from the mixed model ANOVA reveal the main effect of time on comfort scores was significant, ($p = .001$). The results indicate that comfort scores increased over time without regard to groups (within

subjects' measure). Further post hoc tests showed a significant difference exists between time period two (pre-op visit) and time period three (post op visit) $p = .028$. Comfort scores increased significantly in all patients undergoing surgery regardless of group assignment.

This effect suggests that surgery is a powerful intervention for stress urinary incontinence. The literature supports this finding as surgical treatment of stress urinary incontinence generates a high cure rate, defined as a decrease in amount and frequency of urine loss, along with improvement in quality of life and patient satisfaction (DeBeau, 2006; Lukban, 2005). The literature, examined for this study, reveals that immediate and long term improvement in incontinence episodes following surgery is related to an increase in patient satisfaction scores as well as patient report of subjective cure outcomes (Davis et al., 2004; Lukban, 2005; Richter et al., 2005).

None of the studies on women having surgery for stress urinary incontinence, that were identified in the context of this investigation examined comfort as an outcome variable. However, comfort appears to be an appropriate dependent variable and is supported by the results of this study. The results are congruent with the study by Dowd, Kolcaba and Steiner (2000) that reported a significant increase in comfort in patients that received behavioral treatment for urinary incontinence thus improving bladder function and transcending this health stressor.

According to Hullfish et al. (2002) women who have surgery for female stress urinary incontinence and pelvic organ prolapse desire to achieve treatment goals related to social, physical, and psychological domains. A similar study by Trowbridge et al. (2008) found that the main goal of women with stress urinary incontinence is to attain

continence and increase their physical activity. Comparable results in the study by Dowd, Kolcaba and Steiner (2000) indicate that comfort as an outcome, measures the physical, psychospiritual, social, and environmental aspects of urinary incontinence. Therefore a significant increase in comfort scores following treatment for stress urinary incontinence in women is a relevant finding in this study and follows the conceptual framework of comfort theory. That is, members of the health care team, working in collaboration, address the need for treatment of stress urinary incontinence in women through initiation of an intervention thereby enhancing comfort.

The second part of Hypothesis 1 the amount of urine leaks will decrease across time in women having surgery for stress urinary incontinence was not supported. Results from the mixed model ANOVA were not significantly different for the main effect of time ($p = .21$). That is, the amount of urine leakage did not significantly decrease during the three time periods as hypothesized. A similar non-significant result was reported by Jarvis et al (2005) in women undergoing surgery for stress urinary incontinence and/or pelvic organ prolapse.

Pelvic organ prolapse is a contributing factor that should be considered in light of these findings. Examination of the data reveals that some women with pelvic organ prolapse had no objective leakage of urine at time period 1; although they all had diagnoses of stress urinary incontinence confirmed by urodynamic evaluation and were scheduled for the surgical correction procedure. This would account for the lack of significant decrease in urine leak amount at time period 2 and time period 3. According to Mokrzycki, Hatangadi, Zaccardi and Cox (2001) pessaries used to treat pelvic organ prolapse may relieve a partial obstruction and unmask stress urinary incontinence

symptoms. A similar unmasking of incontinence symptoms can occur with surgical repair of prolapse. Schorge et al.(2008) recommends that women undergoing repair of pelvic organ prolapse be evaluated for the presence of “occult” or “latent” stress incontinence by performing urodynamic studies with the prolapse reduced. Thus, even though participants had the diagnosis of stress urinary incontinence, the lack of leakage in the standing position might be attributed to obstruction of the bladder neck by the vaginal prolapse, thus obscuring the true urine leak amount (Hunskaar et al., 2002).

Hypothesis Two

Hypothesis 2 states women in the pelvic floor re-education intervention group will have greater comfort as compared to women in the control group who do not receive the pelvic floor re-education intervention. This hypothesis was derived from theory that proposes a nursing intervention, designed to meet a patient’s needs, will increase comfort (Kolcaba 1995).

In this study, no statistically significant differences were found for the main effect for group ($p = .27$). A review of the literature indicates that pelvic floor re-education is an effective and well known treatment strategy in decreasing incontinence episodes in women with stress urinary incontinence and improving quality of life (Aksac et al., 2003, Aukee et al. 2002; Yoon, Song & Ro, 2003). Similarly, Pages et al. (2001) found that patients who participated in pelvic floor re-education therapy assisted by biofeedback had a stronger muscle contraction and more rapid reduction of leakage episodes than women in the control group. Jarvis et al. (2005) reported a significant difference between groups of women having surgery for stress incontinence and pelvic organ prolapse, in the urinary symptom specific health and quality of life questionnaire. The quality of life scores

showed a statistically significant improvement in the women in the treatment group while the control group did not achieve a statistical significant improvement following surgery (Jarvis et al.). These results reported in the literature are not supported in this study.

Although statistical significance was not achieved in this study the results of a medium effect size ($\eta = .22$) suggest there may be clinical relevance. The effect size is the change or impact made on the dependent variable by the independent variable (Cohen, 1992).

Although the main effect for group did not reach statistical significance, the descriptive statistics of the control and experimental group show a trend toward a difference in comfort score means at the three specified time points. At the first measure, after consent but prior to randomization the two group comfort scores were as follows: Group A (control) had a mean score of 112.8 (SD 16.6) and Group B (experimental) had a mean score of 116.7 (SD 20.5). At the second measure, the pre-operative visit (after the pelvic floor re-education intervention for Group B) the comfort scores for Group A decreased (M = 108.2 , SD 19.7) while the scores for Group B stayed relatively constant (M = 117.3, SD 17.0). The final measure at time period 3 indicated that at the post operative visit both group scores increased considerably: The mean of Group A was 130. 3, (SD 18.8), while the mean of Group B increased to 138.9, (SD 16.9).

The non significant results related to this hypothesis are probably due to a Type II error because of the small sample size. A Type II error is made when a false null hypothesis is accepted (Tabachnick & Fidell, 2006). According to Tabachnick and Fidell the most clear-cut way to avoid a Type II error is to increase the sample size which in

turn will increase the power of the statistical analysis. Thus a power analysis was performed to direct future research.

The sample size required for a future study was guided by a power analysis using the software program G*Power (Version 3.0.10, Dusseldorf, Germany). The primary intent of this power analysis was the outcome of the main effect of group. The medium effect size (.22) that was obtained in this study, for the main effect of group was used for this analysis. Thus, for a significance level of alpha = .05, with a medium effect size of .22, to achieve a power of .80, a total sample size of 86 subjects with 43 in each group will be required. An effect size is considered to be the smallest immediate effect that is clinically meaningful in the target population for the dependent variable, comfort. Power was set to .80, meaning there would be an 80% probability of reaching statistical significance if there is difference between the groups.

Although the testing of this hypothesis did not reach statistical significance the implications for patient care should not be dismissed. Results of this study suggest that surgical correction is the main intervention and has the most impact on enhancing comfort in women with stress urinary incontinence and/or pelvic organ prolapse. However, as Dr. Kegel reported in 1948, performing pelvic muscle exercises before and following surgical correction for vaginal and bladder dysfunction should be used to facilitate recovery and aid in restoring function. Pelvic floor re-education may be an important adjunct therapy for improving physical outcomes and comfort in women having surgery for stress urinary incontinence and pelvic organ prolapse. It is important to note that although the treatment group actually had a larger amount of urine leaks following surgery their comfort scores were higher. This is congruent with the previous

studies that indicate the patient's perception of improvement is not always measured by the absence of leakage (Eladry et al., 2003).

No statistical significance was found for the interaction between group and time ($p = .569$). According to Tabachnick and Fidell (2006) the interaction between group and time is an important analysis because it evaluates whether the dependent variable changed across groups as well as across time. A linear relationship between the two groups in which the treatment group increases steadily over the three time points while the control group remained constant or decreased would be a significant finding. In this study both groups increased between time points two and three, therefore the group by time interaction is not significant.

Hypothesis Three

Hypothesis 3 contended that women in the pelvic floor re-education intervention group will have less stress incontinence as compared to women in the control group who do not receive the pelvic floor re-education intervention. Results of mixed model ANOVA revealed no statistical significant differences for the main effect of time ($p = .20$), main effect of group ($p = .57$) or for the interaction between group and time ($p = .24$) for amount of urine leaks. As mentioned previously the lack of significant results may be attributed to the inability to assess true leakage amount at the first measurement in women who have pelvic organ prolapse.

In addition, quantifying urinary leakage as an outcome measure is difficult because amount of leak is not always a significant subjective indicator of a patient's perception of incontinence. According to Bo, Talseth and Holme (1999) the increased intra-abdominal pressure that is likely to cause leakage during testing might be

considered as too rigorous a physical activity by some women in their everyday daily activities. Thus, even though some women may leak during testing they might consider themselves continent. Bo, Talseth and Holmes suggest that a subjective measurement following treatment might be the best assessment of cure.

Overall responses to the exploratory questions regarding the feasibility of attending the pelvic floor re-education sessions were all positive. All of the participants did not find attending the sessions to be inconvenient and all indicated that they found the sessions helpful in preparing for surgery.

Pelvic floor re-education is a safe and effective treatment option with no adverse consequences. This treatment option is covered by most insurance companies and was well tolerated and accepted by participants in this study. Although results of the main effect of group were not significant the use of pelvic muscle re-education as an adjunct therapy prior to surgery appears to have some merit in enhancing comfort.

Limitations of Study

Limitation of the current study was the small, nonprobability sample of convenience. Due to financial constraints the study was under powered and thus did not reach statistical significance. The size, convenience, and homogeneity of the sample limit the generalizability of this study.

Another limitation was that the measurements and intervention were made without blinding of the researcher to the experimental group which has the potential for bias. However, potential bias was minimized by random assignment of participants and the following of standardized protocol by the investigator.

Short post operative follow-up period of three weeks is a limitation for a number of reasons. At this post operative time point healing is still occurring especially in women with concomitant surgeries and most women have not returned to full daily activities. Measurement of urinary leakage amount at longer follow-up intervals may reveal a decrease in urine leaks over time as healing takes place (Mahajan et al., 2006). Longer follow-up at six and twelve weeks following surgery would confirm the results or uncover more or less favorable results over time.

Recommendations for Future Research

The present study supports the feasibility and importance of conducting a larger study. Cost of the intervention is a major consideration and funding would be instrumental in carrying out a full study with the recommended 86 subjects. Safety and acceptability of the intervention was supported in this study and in the review of the literature.

Recommendations for a future study include a larger sample size, and a longer follow-up period with measurement at 3, 6, and 12 weeks post operative to allow for healing to take place. Also the standard of care, recommended by the practitioners involved in this study, is that patients can resume pelvic muscle exercise following the initial post operative visit. Thus measurement of outcomes at 6 and 12 weeks would supply additional information regarding the effect of the pelvic floor re-education intervention that is resumed after surgery. Demographic variables such as age, weight, etc. can also be compared in a larger study.

In addition, separating the participant groups into women with corrective procedures for stress incontinence alone and women having additional concomitant

pelvic organ prolapse surgery might clarify results. Adding another measurement tool for stress urinary incontinence (i.e., urodynamic evaluation, 24 hour pad test, voiding diary) and reducing pelvic organ prolapse for the pre-surgery measurements would supply a more accurate account of the amount of urine leaks before and following the intervention. Periodic checks of interrater and intrarater reliability need to be performed throughout the measurement of urine leaks to reassess reliability of results.

Significance to Nursing Practice

Nurse Practitioners, in their daily practice, can expect to encounter women whose lives are negatively affected by urinary incontinence. Review of the literature provides nurses with limited evidence in improving comfort in women having surgery for stress incontinence. Advanced practice nurses have the responsibility to evaluate and manage women with urinary incontinence by adopting evidence-based guidelines and designing treatment protocols. The present clinical treatment guidelines for this condition encourage a multifactorial approach including behavioral, bladder training, pelvic muscle exercise and surgery. This study is relevant not only for nursing but for the health care team because treatment options span the disciplines of nursing, physical therapy and surgery. New surgical techniques offer women definitive treatment with minimal complications making surgical option a first choice for more patients. Developing interventions to improve patient outcomes following surgery will increase patient satisfaction and decrease the cost and burden of urinary incontinence.

This study was significant for nursing practice because it measured the effect of a nursing intervention on comfort following a surgical treatment. Thus a more holistic view was explored rather than measuring only physical parameters such as the strength of the

pelvic floor muscles or the absence of leakage. One of the major implications to be drawn from this study is that patients in the intervention group considered the pelvic floor re-education sessions helpful, informative and worth their time. Although the effect of pelvic floor re-education on comfort did not show statistical significance, the clinical significance of the effect size warrants further investigation.

Knowledge gained from this study can be used to direct further research. A full study with adequate sample size and power will contribute to the advancement of nursing science and may translate into improved patient outcomes in the practice settings.

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Appendix A: Paper Towel Test Look Up Table

Look-Up Table for the University of Michigan Paper Towel Test

(please see Miller JM, Ashton-Miller JA, DeLancey JO. "Quantification of Cough-Related Urine Loss Using the Paper Towel Test" Obstet. Gynecol. 91:705-9, 1998.

(please direct questions to jaam@umich.edu)

This Look-up Table was obtained from our data collated from tests using the brown paper towel, Item #219-24 supplied by Handifold Towel, Fort Howard Corp., Green Bay, Wisconsin, U.S.A.. Note: If you use a different paper towel, then you must calibrate it in the way described in the above article.)

Useage Instructions:

1) Ask woman to perform the test with a symptomatically full bladder. To achieve this ask her not to void for 2 hrs before visit, and drink 0.5 liters of water 1 hour before arrival. She should be able to void at least 100 mL after the test is complete.

2). First, have the patient dry her perineum thoroughly in the standing position.

3). Ask her to hold the a new towel lightly against her perineum.

4). Ask her to take a deep breath and cough "as hard as she can". Repeat two more times

5). Take the towel and trace the wetted area with a ballpoint pen 10-15 s after conducting the test.

6). Using a metric ruler, measure in cm the length (a) and width (b) of the wetted area, and note the results on data sheet. You should measure these lengths to the nearest tenth of a centimeter, i.e, 3.1 cm).

7). To find the wetted area you will use the formula for the area of an ellipse. (As you will recall the area of an ellipse in Pi times half the length times half the width.) Hence you multiply the length (in cm) by the width (in cm), multiply that result by 3.14, and then divide the result by 4 to obtain the wetted area in units of square centimeters.

8) Now use the table below to look up the volume of urine corresponding to the closest value of area to that which you measured. If you wish you may interpolate between adjacent area values.

9) As an example, suppose you calculated the wetted area as 19.5 sq. cms. Then you use the table to find that the leakage volume was approximately 0.55 mls (equivalent to 11 drops from an eye drop pipette). If, for more accuracy, you wanted to interpolate the volume, then the volume would be = 0.55+ (0.60-0.55)*(19.5-19.2)/(21.2-19.2) = 0.5575 which should be rounded to two decimal places, i.e. 0.56 mls)

Volume (mls)	Volume (Drops of Water)	Ellipse-Modeled Area * pi X radius lgth X wdth (units: square cms)
0.05	1	2.7
0.10	2	4.0
0.15	3	6.7
0.20	4	7.3
0.25	5	8.7
0.30	6	12.0
0.35	7	12.9
0.40	8	15.3
0.45	9	16.8
0.50	10	17.9

0.55	11	19.2
0.60	12	21.2
0.65	13	21.7
0.70	14	25.0
0.75	15	26.6
0.80	16	27.9
0.85	17	29.3
0.90	18	32.5
0.95	19	33.8
1.00	20	33.6
1.25	25	39.9
1.50		
2.00		
2.50	50	68.2
3.00		
3.50		
3.75	75	84.3
4.00		
4.50		
5.00	100	95.7
5.50		
6.00		
6.25	125	108.5
6.50		
7.00		
7.50	150	171.2
8.00		
8.50		
8.75	175	165.8
9.00		
9.50		
10.00	200	170.7
11.25	225	168.4

**Provides a reasonable estimate

Appendix B: Urinary Incontinence and Comfort Frequency Questionnaire

Date_____

Code _____

IMMEDIATE OUTCOME (UICQ)

Thank you VERY MUCH for helping us in our study about feelings associated with urinary incontinence. Below are statements that pertain to your feelings. Six numbers are provided for each question: please circle the number you think most closely matches your feelings at the moment you are answering the questions.

6 is strongly agree 1 is strongly agree

---

1. I feel good about myself..... 6 5 4 3 2 1
2. It helps to talk to people about my urinary incontinence..... 6 5 4 3 2 1
3. I worry about being able to find a bathroom when I go out..... 6 5 4 3 2 1
4. I am just as attractive physically as I always way..... 6 5 4 3 2 1
5. I feel tense..... 6 5 4 3 2 1
6. I'm afraid to go visit my friends or family..... 6 5 4 3 2 1
7. I don't have enough information about my urinary incontinence..... 6 5 4 3 2 1
8. I think about my bladder all the time..... 6 5 4 3 2 1
9. I don't know anyone else with this problem..... 6 5 4 3 2 1
10. I am tired..... 6 5 4 3 2 1
11. I am able to copy with my urinary patterns..... 6 5 4 3 2 1
12. My home smells clean..... 6 5 4 3 2 1
13. I am able to sleep well..... 6 5 4 3 2 1
14. Life is a struggle right now..... 6 5 4 3 2 1
15. I enjoy going shopping..... 6 5 4 3 2 1
16. I find a lot of meaning in my life..... 6 5 4 3 2 1
17. Urinary incontinence is a challenge I can meet..... 6 5 4 3 2 1

18. I get anxious and fearful about going out 6 5 4 3 2 1
19. I am afraid of what is next 6 5 4 3 2 1
20. No one understands me 6 5 4 3 2 1
21. I drink very little fluids 6 5 4 3 2 1
22. I feel out of control 6 5 4 3 2 1
23. I have a favorite person(s) who makes me feel cared for 6 5 4 3 2 1
24. I enjoy having people over to my house 6 5 4 3 2 1
25. I feel physically fit 6 5 4 3 2 1
26. I am aware of the effects of different fluids on my bladder 6 5 4 3 2 1
27. I feel clean and fresh 6 5 4 3 2 1

Appendix C: Demographic Data Sheet

Instructions: Please check the appropriate blank or fill in the space.

1. Age at present time _____

2. How many children do you have? _____

3. What ethnicity do you consider yourself? (please check one)

   3.1 _____ White

   3.2 _____ African American

   3.3 _____ Caribbean American

   3.4 _____ Latino

   3.5 _____ Asian

   3.6 _____ Native American

   3.7 _____ Other (please specify) : _____

4. What is your current marital status? (please check one)

4.1 _____ married

4.2 _____ widowed

4.3 _____ separated

4.4 _____ divorced

4.5 _____ single

4.6 _____ domestic partner

Demographic Data Sheet (continued)

1. What is your highest level of education? (please check one)

    5.1 _____ Grade school diploma

    5.2 _____ High school diploma

    5.3 _____ Some college

    5.4 _____ Associate degree

    5.5 _____ Baccalaureate degree

    5.6 _____ Master's degree

    5.7 _____ Professional doctoral degree (MD, JD, DDS,)

    5.8 _____ Doctorate (PhD, EdD, DNS, other research doctorate)

2. What is your household income?

    4.1 _____ less than $10,000

    4.2 _____ $10,000 to $30,000

    4.3 _____ $30,000 to 50,000

    4.4 _____ $50,000 to $75,000

    4.5 _____ more than $75,000

The following questions will be completed by the investigator.

1. Weight: _____

2. Diagnosis: _____

3. Surgical Procedures: _____

Appendix D: Exploratory Questions

Did you find it difficult to attend the 2 biofeedback sessions? Yes No

If yes, please explain:

Did you find the sessions helpful? Yes No

Please explain:

Comments:

Appendix E: IRB Approvals and Consent

September 4, 2008

Joan Zaccardi, MS, APRN, BC
254 Easton Avenue
New Brunswick, NJ 08901

RE: Our Study # 07:51

Protocol Title: The Effect of Pelvic Floor Re-Education on Comfort in Women Having Surgery for Incontinence

LAST RENEWAL DATE: 8/27/2008

Dear Ms. Zaccardi:

The Committee for the Protection of Human Subjects in Research reviewed the above referenced study at their meeting held on 9/4/2008. All requirements as set forth by Saint Peter's University Institutional Review Board have been fulfilled and we are pleased to advise that your Continuing Review Report was approved. You may continue with your project as of this date.

The next Continuing Review Report for this study is due: 2/26/2009

Please Note: Enrolled subjects must sign the latest approved consent form (if applicable).

Sincerely,

Anne Koons, M.D.
Chairperson,
Committee for the Protection
of Human Subjects in Research

cc: CPHSR Study File

SAINT PETER'S
UNIVERSITY HOSPITAL

254 Easton Avenue, PO Box 591
New Brunswick, NJ 08903-0591
732-745-8600 • www.saintpetersuh.com

March 3, 2008

Joan Zaccardi MS, APRN, BC
254 Easton Avenue
New Brunswick NJ 08901

Meeting Date: 2/28/2008

RE: Our Study # 07:51

Protocol Title: The Effect of Pelvic Floor Re-Education on Comfort in Women Having Surgery for Incontinence

Dear Ms. Zaccardi:

The Committee for the Protection of Human Subjects in Research (CPHSR) has reviewed your Research Protocol, ***The Effect of Pelvic Floor Re-Education on Comfort in Women Having Surgery for Incontinence***, and The Informed Consent. All requirements as set forth by the Saint Peter's University Hospital's Institutional Review Board have been fulfilled.

Please be advised that the Committee has approved your proposal ***The Effect of Pelvic Floor Re-Education on Comfort in Women Having Surgery for Incontinence*** and Informed Consent, and that you may commence with the project as of this date.

A written update (Continuing Review) on the progress of the study is required no later than 8/27/2008, and at **6** month periods thereafter. Additionally, a list of subjects should be submitted with each progress report. Any and all changes expected for this research proposal must be submitted to the CPHSR for review and approval prior to implementation.

Page 2

Zaccardi, Joan MS, APRN, BC
The Effect of Pelvic Floor Re-Education on Comfort in Women Having Surgery for Incontinence

A copy of the entire signed consent form must be placed directly into the study patient chart.

Please note: All study related incidents of a serious nature must be reported to the chairperson of the committee within 24 hours.

Sincerely,

Anne Koons, M.D.
Chairperson,
Committee for the Protection
Of Human Subjects in Research

cc: CPHSR Study File

Attachment(s):

CPHSR Approved:

- **Study Protocol**
- **The Informed Consent**

IRB AUTHORIZATION AGREEMENT

Name and Address of Institution or Organization Providing IRB Review (Institution A):
Name and address of IRB: Saint Peter's University Hospital
254 Easton Avenue
New Brunswick, New Jersey, 08901
Federal Wide Assurance Number: FWA 00007321

Name of Institution Relying on the Designated IRB (Institution B):
Drexel University
1601 Cherry Street, Suite 10444, 3 Parkway
Philadelphia, PA 19102
Federal Wide Assurance Number: FWA 00001852

The Officials signing below agree that Drexel University will rely on the designated IRB of Institution A for review and continuing oversight of its human subjects research described below.

This agreement is limited to the following specific protocol(s):

Name of Research Protocol: "The Effect of Pelvic Floor Re-education on Comfort in Women Having Surgery for Incontinence"

Study #: 07:51
Name of Principal Investigator (Institution A): Joan Zaccardi, MS, APRN, BC
Name of Principal Investigator (Institution B): Linda Wilson, Ph.D.

The protocol reviewed and approved by the IRB of Institution A will include a description of the research to be conducted at Institution B. Principal Investigators at both Institutions will maintain current copies the IRB approved protocol. Institution A will conduct this research in accord with the terms and conditions of its OHRP-approved Assurance and will provide relevant minutes of its IRB meetings to Institution B upon request. Institution B will conduct this research in accord with the terms and conditions of its OHRP-approved Assurance. This agreement will be kept on file at both Institutions and will be available to OHRP upon request.

Authorizing Officials

Saint Peter's University Hospital

x Anne Koons MD

Anne Koons, MD
Chairperson
Committee for the Protection
of Human Subjects in Research
254 Easton Ave.
New Brunswick, NJ 08901
732-745-8600
cphsr@saintpetersuh.com

4/9/08
Date

Drexel University

x Sreekant Murthy, Ph.D

Sreekant Murthy, Ph.D.
Vice Provost for Research Compliance
Drexel University College of Medicine
1601 Cherry Street, Suite 10444, 3 Parkway
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215-255-7858 (Phone), 215-255-7874 (Fax)
s.murthy@drexel.edu (e-mail)

4/7/08
Date

SAINT PETER'S UNIVERSITY HOSPITAL
A MEMBER OF SAINT PETER'S HEALTHCARE SYSTEM
254 Easton Avenue, PO Box 591
New Brunswick, NJ 08903-0591
732-745-8600 • www.saintpetersuh.com

Consent to Take Part in a Research Study

Title of Research: The Effect of Pelvic Floor Re-education on Comfort in Women Having Surgery for Incontinence

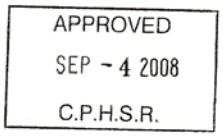
Investigators' Name: Joan E. Zaccardi, MS, APRN, BC

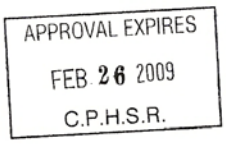
Co-Investigators: Mark L. Mokrzycki, MD
Linda B. Wilson, RN, PhD, CAPA, BC, CNE

Participant's Name: _____

Introduction: This is a long and an important document. If you sign it, you will be authorizing Saint Peter's University Hospital and its researchers to perform a research study on you regarding treatment for urinary incontinence. You should take your time and carefully read it. You can also take a copy of this consent form to discuss with your family members, physician, attorney or any one else you would like to, before you sign it. Do not sign it unless you are comfortable with participating in this study.

Purpose of Study: You are being asked to participate in a research study. This study is being done by a Doctor of Nursing Practice student to fulfill a requirement for graduation. The purpose of this study is to find out if pelvic muscle exercise affects comfort and urine leakage in women having surgery for incontinence. This is important because urinary incontinence affects many women and can be a cause of discomfort and embarrassment. Sixty female subjects with a diagnosis of stress urinary incontinence opting for surgical correction will be recruited for the study. Criteria for inclusion in the study will consist of adult women (age ≥ 35-80) who have a diagnosis of stress urinary incontinence and are scheduled for corrective surgery; those women undergoing concomitant surgical procedures will also be eligible.





Procedures: I understand that the following things will be done during the study:

If I participate in this study I will first sign the consent form. Background information about me and my medical history will be collected. I will be asked to fill out a questionnaire. I will be given a paper towel test. For this test I will come to the office with a full bladder.

I will not void for at least 2 hours before my appointment and I will drink 2 eight ounce glasses of fluid about 1 hour before testing. While standing, I will place a sanitary pad covered by a paper towel in my panties. I will be instructed to cough 3 times deeply. This will be repeated 3 times with a 10 second rest in between. This test and the questionnaire will be repeated at my pre-operative visit and again following surgery at my post-operative visit.

After signing the research consent form and completing the paper towel test and the questionnaire, I will be assigned to a group. If I am assigned to Group A I will receive information regarding the surgery, along with brochures about the surgery and instruction on post-operative care. If I am assigned to Group B, in addition to the above information, I will attend 2 pelvic exercise sessions. Each session will be approximately 60 minutes. I will be given information about my bladder and taught pelvic floor exercises using biofeedback. I will be instructed to place a sensor in my vagina and 3 small sticky pads on my abdomen. I will be connected to the SRS Medical Orion biofeedback machine. I will practice pelvic muscle tightening and relaxing. I will be given information about practicing these exercises at home.

Benefits: There may be no direct benefits to me from participating in this study. However, I might gain knowledge about function of the bladder.

Risks:

- During the placement of the sensor I may feel some pressure. I may have vaginal irritation, discomfort or pain from using the sensor.
- There may be risks and discomforts that are not yet known.
- I will be able to use lubricating jelly to minimize discomfort from the sensor. I can discontinue using the sensor at any time.

Alternative procedures/treatment: The alternative is <u>not</u> to participate in the study.

Pregnancy Statement: I may not take part in this study if I am breastfeeding or are pregnant. If I am pregnant or breastfeeding, there may be risks to the baby and me that are not know at this time.

I must agree not to become pregnant during my participation in this study. If I think I have become pregnant, I must inform my study doctor immediately.

Compensation for Injury: Medical therapy will be arranged by Joan Zaccardi, APRN for any physical injuries sustained as a direct consequence of your participation in this research.

Your health insurance carrier or other third part payor will be billed for the cost of this medical therapy. All claims for any physical injury shall be made to the researcher who will arrange for review in accordance with hospital policy.

No other compensation is available. **Saint Peter's University Hospital will not be responsible for compensation or free treatment if injury occurs as a result of the study**.

New Findings: You will receive any information relating to significant new findings that are uncovered or develop during this study which relate to your willing participation in the study.

Voluntary Participation: You understand that being in this study is voluntary. Your health care will not be affected in any way if you decline to be in or later decide to withdraw from the study

Termination: You may be required to stop participation in the study before the end for any of the following reasons:

- Change in your medical condition
- If all or part of the study is discontinued for any reason by the investigator, hospital authorities, or government agency.
- Other reasons, including new information available to the investigator or harmful unforeseen reactions experienced by you or other subjects in this study.

Cost: You and your insurance will not be charged for any cost related to this study. (i.e. paper towel test, filling out questionnaires, pelvic muscle exercise).

Stipend/Reimbursement: At the completion of the study (the post operative visit) you will receive a $25.00 gift card to Target. You will also receive complimentary parking for all visits to the Center related to this research study ($3.00/visit).

Confidentiality and Privacy: By signing this form, you agree that your health information may be used and disclosed during this research study. We will only collect information that is needed for the research study. Your health information will only be used and given out as explained in this consent form or as permitted by law. In any publication or presentation of research results, your identity will be kept confidential.

The following personal health information about you will be collected and used during the research study and may be given out to others:

- Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
- Information in medical records located in the Health Center for Women.

The research study investigator and other authorized individuals involved in the research study at Saint Peter's University Hospital will see your health information and may give out

your health information during the research study. These include the research investigator and the research staff, the Institutional Review Board at Saint Peter's University Hospital (Committee for the Protection of Research in Human Subjects) and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly. Other persons and organizations outside of Saint Peter's University Hospital may see and use your health information during this research study. These include:

- Governmental entities that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration
- An outside institutional review board.

Whom to Contact:
If you have any questions or wish to contact the study investigators you can contact Joan E. Zaccardi and or Dr. Mark L. Mokrzycki at the Health Center for Women at 732-937-6003. If you have any questions about your rights as a research subject, you may contact Anthony Costabile at the Saint Peter's University Hospital's Internal Review Board, The Committee for the Protection of Human Subjects in Research (CPHSR), Office at (732) 745-8600, extension 8175.

I have read or have had read to me in my first language the above information. The content and meaning of this information has been explained to me and I understand fully. I have been given an opportunity to ask any questions that I may have, and all such questions have been answered to any satisfaction.

I will be given a copy of this consent to keep.

Consent:

- **I have been informed of the reasons for this study**
  - **I have had the study explained to me**
  - **I have had all of my questions answered**
  - **I have carefully read this consent form, have initialed each page, and have received a signed copy**
  - **I authorize the use and disclosure of my personal health information as explained in this consent form.**
  - **I give consent voluntarily.**

The undersigned health care provider has assured me he/she will answer any questions I have concerning the procedure, device or drug involved. I am also aware that I am free to withdraw from participation in this study at any time.

_____ _____ _____

(Date) (Time) (Signature – Patient or Legal Representative

_____

Relationship to Patient

_____ _____

(Witness to the Signature) (Date)

I have explained the objectives of this study listed above and indicated any knows side effects to the above patient or legal representative. I have also assured the patient or legal representative that I will answer any inquiries concerning the procedure, device, or drug involved, and that the patient is free to withdraw from this study at any time.

_____ _____

(Date) (Signature obtained by Investigator)

Vita

Joan E. Zacardi

EXPERIENCE

Urogynecology Arts of New Jersey, 620 Cranbury Road, Suite 219, East Brunswick, N. J. 08816
Practice manager/nurse practitioner – manager of urogynecology practice as well as patient evaluation and treatment, urodynamic testing,and pelvic floor re-education. 2008 – present.

Saint Peter's University Hospital, Health Center for Women, CARES 3rd floor, 254 Easton Avenue, New Brunswick, N. J. 08903. Nurse Manager/Nurse Practitioner, the Health Center for Women, 1998 – 2008.

Rutgers the State University of New Jersey Faculty, Continuing Education: Basic Physical Assessment 1999-2001

Clara Maass Medical Center, Belleville, N. J. Parent Educator/ Clinician - Department of Maternal Child Health 1995–1998

Staff Nurse, 1974–1995

Private Practice, North Arlington, N. J. 1975–1985 Childbirth Educator

EDUCATION

Doctor of Nursing Practice, 2008, Drexel University, Philadelphia, Pa.

Master of Science: Nursing, 1999, Rutgers, The State University of NJ, Newark, NJ.

Bachelor of Science: Nursing, 1996, Monmouth University, West Long Branch, N. J.

Diploma: Nursing 1974, Clara Maass Memorial Hospital School of Nursing, Belleville, NJ.

PUBLICATIONS

Zaccardi, J. E. & Cox, S. B. (2005). "A nurse practitioner's approach to female urinary incontinence." Journal of Women's Health, 14(4) 366 (poster abstract).

Cox, S. B. & Zaccardi, J. E. (2005). "The diagnosis and management of interstitial cystitis." Journal of Women's Health, 14(4) 369 (poster abstract)

Aguilar, V., Zaccardi, J., Falk, M., Hatangadi, S., Mokrzycki, M., "Pelvic Organ Prolapse Quantification (POP-Q) as a predictor of successful pessary management for women with pelvic organ prolapse." ICS 2005 Scientific Programme 'Read by Title'. ICS 2005 Abstract CD-ROM, ICS Website.

Zaccardi, J. E. & Cox, S. B. (2004). " Female Urinary Incontinence Evaluation and Management" Lifelines 8(4), 326-332.

Mokrzycki, M. L., Hatangadi, S., Zaccardi, J. E., Cox, B. E. (2000). "Preexisting stress urinary incontinence: a predictor of discontinuation with pessary management" Journal of lower genital tract disease 5(4), 204-207.

AWARDS and HONORS

Drexel University 2007 Clinical Scholar

Drexel University 2007 Verbal Qualifying Exam – passed with distinction